ATTACHMENT 27

Risk Assessment Guidance for Superfund, Volume I
Human Health Evaluation Manual (Part A)
(EPA/540/1-89/002)
December 1989

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Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A)

Interim Final

Office of Emergency and Remedial Response
U.S. Environmental Protection Agency
Washington, DC 20450

NOTICE

The policies and procedures set forth here are intended solely as guidance to EPA and other government employees and contractors. This guidance does not constitute rulemaking by the Agency, and cannot be relied on to create a substantive or procedural right enforceable by any party in litigation with the United States. EPA may take action that is at variance with the policies and procedures in this manual and may change them at any time without public notice.

This interim final guidance is based on policies in the proposed revisions to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which were published on December 21, 1988 (53 *Federal Register* 51394). The final NCP may adopt policies different than those in this manual and should, when promulgated, be considered the authoritative source. A final version of this manual will be published after the revised NCP is promulgated.

Following the date of its publication, this manual is intended to be used as guidance for all human health risk assessments conducted as part of Superfund remedial investigations and feasibility studies. Issuance of this manual does not invalidate human health risk assessments completed before (or in progress at) the publication date and based on previously released Agency guidance.

ABOUT THE REVISION . . .

WHAT IT IS

EPA's *Human Health Evaluation Manual* is a revision of the *Superfund Public Health Evaluation Manual* (SPHEM; October 1986); it is Volume I of the two-volume set called *Risk Assessment Guidance for Superfund.* This manual has three main parts: the baseline risk assessment (Part A); refinement of preliminary remediation goals (Part B); and evaluation of remedial alternatives (Part C). (Only Part A is included in the first distribution; see below.)

WHO IT'S FOR

Risk assessors, risk assessment reviewers, remedial project managers (RPMs), and risk managers involved in Superfund site cleanup activities will benefit from this revision.

WHAT'S NEW

This revision builds upon the process established in SPHEM and provides more detailed guidance on many of the procedures used to assess health risk. New information and techniques are presented that reflect the extensive Superfund program experience conducting health risk assessments at Superfund sites. Policies established and refined over the years -- especially those resulting from the proposed National Oil and Hazardous Substances Pollution Contingency Plan (NCP) -- have been updated and clarified. Additionally, the links between the human health evaluation, the environmental evaluation, and the remedial investigation/feasibility study (RI/FS) have been strengthened.

In Part A you will find:

For the risk assessor -- Updated procedures and policies, specific equations and variable values for estimating exposure, and a hierarchy of toxicity data sources.

For the risk assessment reviewer -- A baseline risk assessment outline for consistent presentation of risk information and format, and a reviewer's checklist to ensure appropriate quality and content of the risk assessment.

For the RPM -- A comprehensive overview of the risk assessment process in the RI/FS, a checklist for RPM involvement throughout the process, and a complete index for quick reference.

For the risk manager -- An expanded chapter on risk characterization (Chapter 8) to help summarize and present risk information for the decision-maker, and more detailed descriptions of uncertainties in the assessment.

DISTRIBUTION PLAN

This manual is being distributed as an interim final document while the proposed NCP is being finalized. After the final NCP is published, the manual will be updated and finalized. Parts B and C -- which were not distributed as interim final because they are highly dependent on possible revisions to the NCP -- will be added. Periodically, updates of portions of the manual will be distributed.

WHERE TO SEND COMMENTS

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PREFACE

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) requires that actions selected to remedy hazardous waste sites be protective of human health and the environment. CERCLA also mandates that when a remedial action results in residual contamination at a site, future reviews must be planned and conducted to assure that human health and the environment continue to be protected. As part of its effort to meet these and other CERCLA requirements, EPA has developed a set of manuals, together entitled *Risk Assessment Guidance for Superfund*. The *Human Health Evaluation Manual* (Volume I) provides guidance for developing health risk information at Superfund sites, while the *Environmental Evaluation Manual* (Volume II) provides guidance for environmental assessment at Superfund sites. Guidance in both human health evaluation and environmental assessment is needed so that EPA can fulfill CERCLA's requirement to protect human health and the environment.

The *Risk Assessment Guidance for Superfund* manuals were developed to be used in the remedial investigation/feasibility study (RI/FS) process at Superfund sites, although the analytical framework and specific methods described in the manuals may also be applicable to other assessments of hazardous wastes and hazardous materials. These manuals are companion documents to EPA's *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (October 1988), and users should be familiar with that guidance. The two Superfund risk assessment manuals were developed with extensive input from EPA workgroups comprised of both regional and headquarters staff. These manuals are interim final guidance; final guidance will be issued when the revisions proposed in December 1988 to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) become final.

Although human health risk assessment and environmental assessment are different processes, they share certain common information needs and generally can use some of the same chemical sampling and environmental setting data for a site. Planning for both assessments should begin during the scoping stage of the RI/FS, and site sampling and other data collection activities to support the two assessments should be coordinated. An example of this type of coordination is the sampling and analysis of fish or other aquatic organisms; if done properly, data from such sampling can be used in the assessment of human health risks from ingestion and in the assessment of damages to and potential effects on the aquatic ecosystem.

The two manuals in this set target somewhat different audiences. The *Environmental Evaluation Manual* is addressed primarily to remedial project managers (RPMs) and on-scene coordinators (OSCs), who are responsible for ensuring a thorough evaluation of potential environmental effects at sites. The *Environmental Evaluation Manual* is not a detailed "how-to" type of guidance, and it does not provide "cookbook" approaches for evaluation. Instead, it identifies the kinds of help that RPMs/OSCs are likely to need and where they may find that help. The manual also provides an overall framework to be used in considering environmental effects. An environmental evaluation methods compendium published by EPA's Office of Research and Development, *Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document* (EPA/600/3-89/013), is an important reference to be used with the manual.

The *Human Health Evaluation Manual* is addressed primarily to the individuals actually conducting health risk assessments for sites, who frequently are contractors to EPA, other federal agencies, states, or potentially responsible parties. It also is targeted to EPA staff, including those responsible for review and oversight of risk assessments (e.g., technical staff in the regions) and those responsible for ensuring adequate evaluation of human health risks (i.e., RPMs). The *Human Health Evaluation Manual* replaces a previous EPA guidance document, *The Superfund Public Health Evaluation Manual* (October 1986), which should no longer be used. The new manual

incorporates lessons learned from application of the earlier manual and addresses a number of issues raised since the earlier manual's publication. Issuance of the new manual does not invalidate human health risk assessments completed before (or in progress at) the publication date.

The *Human Health Evaluation Manual* provides a basic framework for health risk assessment at Superfund sites, as the *Environmental Evaluation Manual* does for environmental assessment. The *Human Health Evaluation Manual* differs, however, by providing more detailed guidance on many of the procedures used to assess health risk. This additional level of detail is possible because of the relatively large body of information, techniques, and guidance available on human health risk assessment and the extensive Superfund program experience conducting such assessments for sites. Even though the *Human Health Evaluation Manual* is considerably more specific than the *Environmental Evaluation Manual*, it also is not a "cookbook," and proper application of the guidance requires substantial expertise and professional judgment.

ACKNOWLEDGEMENTS

This manual was developed by the Toxics Integration Branch (TIB) of EPA's Office of Emergency and Remedial Response, Hazardous Site Evaluation Division. Linda Cullen provided overall project management, contract supervision, and technical coordination for the project under the direction of Bruce Means, Chief of TIB's Health Effects Program.

The EPA Workgroup (comprised of members listed on page iv) provided valuable input regarding the organization, content, and policy implications of the manual throughout its development. The project manager especially wishes to acknowledge the assistance of the Workgroup Subcommittee Chairpersons: Rebecca Madison, Bruce Means, Sue Norton, Georgia Valaoras, Craig Zamuda, and Larry Zaragoza.

Other significant contributors to the manual included Joan Fisk, Michael Hurd, and Angelo Carasea of the Analytical Operations Branch (Office of Emergency and Remedial Response); Paul White, Anne Sergeant, and Jacqueline Moya of the Exposure Assessment Group (Office of Research and Development); and Barnes Johnson of the Statistical Policy Branch (Office of Policy, Planning, and Evaluation). In addition, many thanks are offered to the more than 60 technical and policy reviewers who provided constructive comments on the document in its final stages of development.

ICF Incorporated provided technical assistance to EPA in support of the development of this manual, under Contract No. 68-01-7389.

Robert Dyer, Chief of the Environmental Studies and Statistics Branch, Office of Radiation Programs, served as project manager for Chapter 10 (Radiation Risk Assessment Guidance), with assistance from staff in the Bioeffects Analysis Branch and the regional Radiation Program Managers. Chapter 10 was prepared by S. Cohen and Associates, Incorporated (S.C&A), under Contract No. 68-02-4375.

CHAPTER 1

INTRODUCTION

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA, or "Superfund"), establishes a national program for responding to releases of hazardous substances into the environment.[1] The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) is the regulation that implements CERCLA.[2] Among other things, the NCP establishes the overall approach for determining appropriate remedial actions at Superfund sites. The overarching mandate of the Superfund program is to protect human health and the environment from current and potential threats posed by uncontrolled hazardous substance releases, and the NCP echoes this mandate.

To help meet this Superfund mandate, EPA's Office of Emergency and Remedial Response has developed a human health evaluation process as part of its remedial response program. The process of gathering and assessing human health risk information described in this manual is adapted from well-established chemical risk assessment principles and procedures (NAS 1983; CRS 1983; OSTP 1985). It is designed to be consistent with EPA's published risk assessment guidelines (EPA 1984; EPA 1986a-e; EPA 1988a; EPA 1989a) and other Agency-wide risk assessment policy. The *Human Health Evaluation Manual* revises and replaces the *Superfund Public Health Evaluation Manual* (EPA 1986f).[3] It incorporates new information and builds on several years of Superfund program experience conducting risk assessments at hazardous waste sites. In addition, the *Human Health Evaluation Manual* together with the companion *Environmental Evaluation Manual* (EPA 1989b) replaces EPA's 1985 *Endangerment Assessment Handbook*, which should no longer be used (see Section 2.2.1).

The goal of the Superfund human health evaluation process is to provide a framework for developing the risk information necessary to assist decision-making at remedial sites. Specific objectives of the process are to:

- provide an analysis of baseline risks[4] and help determine the need for action at sites;
- provide a basis for determining levels of chemicals that can remain onsite and still be adequately protective of public health;
- provide a basis for comparing potential health impacts of various remedial alternatives; and
- provide a consistent process for evaluating and documenting public health threats at sites.

The human health evaluation process described in this manual is an integral part of the remedial response process defined by CERCLA and the NCP. The risk information generated by the human health evaluation process is designed to be used in the remedial investigation/feasibility study (RI/FS) at Superfund sites. Although risk information is fundamental to the RI/FS and to the remedial response program in general, Superfund site experience has led EPA to balance the need for information with the need to take action at sites quickly and to streamline the remedial process. Revisions proposed to the NCP in 1988 reflect EPA program management principles intended to promote the efficiency and effectiveness of the remedial response process. Chief among these principles is a bias for action. EPA's *Guidance for Conducting Remedial*

Investigations and Feasibility Studies Under CERCLA (EPA 1988b) also was revised in 1988 to incorporate management initiatives designed to streamline the RI/FS process and to make information collection activities during the RI more efficient. The *Risk Assessment Guidance for Superfund*, of which this *Human Health Evaluation Manual* is Volume I,[5] has been developed to reflect the emphasis on streamlining the remedial process. The *Human Health Evaluation Manual* is a companion document to the RI/FS guidance. It provides a basic framework for developing health risk information at Superfund sites and also gives specific guidance on appropriate methods and data to use. Users of the *Human Health Evaluation Manual* should be familiar with the RI/FS guidance, as well as with other guidances referenced throughout later chapters of this manual.

The *Human Health Evaluation Manual* is addressed primarily to the individuals actually conducting human health evaluations for sites (frequently contractors to EPA, other federal agencies, states, or potentially responsible parties). It also is targeted to EPA staff responsible for review and oversight of risk assessments (e.g., technical staff in the regions) and those responsible for ensuring an adequate evaluation of human health risks (i.e., remedial project managers, or RPMs). Although the terms risk assessor and risk assessment reviewer are used in this manual, it is emphasized that they generally refer to teams of individuals in appropriate disciplines (e.g., toxicologists, chemists, hydrologists, engineers). It is recommended that an appropriate team of scientists and engineers be assembled for the human health evaluation at each specific site. It is the responsibility of RPMs, along with the leaders of human health evaluation teams, to match the scientific support they deem appropriate with the resources at their disposal.

Individuals having different levels of scientific training and experience are likely to use the manual in designing, conducting, and reviewing human health evaluations. Because assumptions and judgments are required in many parts of the analysis, the individuals conducting the evaluation are key elements in the process. The manual is not intended to instruct non-technical personnel how to perform technical evaluations, nor to allow professionals trained in one discipline to perform the work of another.

KEY PLAYERS IN SUPERFUND SITE RISK ASSESSMENT/ RISK MANAGEMENT

Risk Assessor. The individual or team of individuals who actually organizes and analyzes site data, develops exposure and risk calculations, and prepares human health evaluation (i.e., risk assessment) reports. Risk assessors for Superfund sites frequently are contractors to EPA, other federal agencies, states, or potentially responsible parties.

Risk Assessment Reviewer. The individual or team of individuals within an EPA region who provides technical oversight and quality assurance review of human health evaluation activities.

Remedial Project Manager (RPM). The individual who manages and oversees all RI/FS activities, including the human health evaluation, for a site. The RPM is responsible for ensuring adequate evaluation of human health risks and for determining the level of resources to be committed to the human health evaluation.

Risk Manager. The individual or group of individuals who serves as primary decision-maker for a site, generally regional Superfund management in consultation with the RPM and members of the technical staff. The identity of the risk manager may differ from region to region and for sites of varying complexity.

The *Human Health Evaluation Manual* admittedly cannot address all site circumstances. Users of the manual must exercise technical and management judgment, and should consult with EPA regional risk assessment contacts and appropriate headquarters staff when encountering unusual or particularly complex technical issues.

The first three chapters of this manual provide background information to help place the human health evaluation process in the context of the Superfund remedial process. This chapter (Chapter 1) summarizes the human health evaluation process during the RI/FS. The three main parts of this process -- baseline risk assessment, refinement of preliminary remediation goals, and remedial alternatives risk evaluation -- are described in detail in subsequent chapters. Chapter 2 discusses in a more general way the role of risk information in the overall Superfund

remedial program by focusing on the statutes, regulations, and guidance relevant to the human health evaluation. Chapter 2 also identifies and contrasts Superfund studies related to the human health evaluation. Chapter 3 discusses issues related to planning for the human health evaluation.

1.1 OVERVIEW OF THE HUMAN HEALTH EVALUATION PROCESS IN THE RI/FS

Section 300.430 of the proposed revised NCP reiterates that the purpose of the remedial process is to implement remedies that reduce, control, or eliminate risks to human health and the environment. The remedial investigation and feasibility study (RI/FS) is the methodology that the Superfund program has established for characterizing the nature and extent of risks posed by uncontrolled hazardous waste sites and for developing and evaluating remedial options. The 1986 amendments to CERCLA reemphasized the original statutory mandate that remedies meet a threshold requirement to protect human health and the environment and that they be cost-effective, while adding new emphasis to the permanence of remedies. Because the RI/FS is an analytical process designed to support risk management decision-making for Superfund sites, the assessment of health and environmental risk plays an essential role in the RI/FS.

This manual provides guidance on the human health evaluation activities that are conducted during the RI/FS. The three basic parts of the RI/FS human health evaluation are:

(1) baseline risk assessment (described in Part A of this manual);

(2) refinement of preliminary remediation goals (Part B); and

(3) remedial alternatives risk evaluation (Part C).

Because these risk information activities are interwined with the RI/FS, this section describes those activities in the context of the RI/FS process. It relates the three parts of the human health evaluation to the stages of the RI/FS, which are:

- project scoping (before the RI);
- site characterization (RI);
- establishment of remedial action objectives (FS);
- development and screening of alternatives (FS); and
- detailed analysis of alternatives (FS).

Although the RI/FS process and related risk information activities are presented in a fashion that makes the steps appear sequential and distinct, in practice the process is highly interactive. In fact, the RI and FS are conducted concurrently. Data collected in the RI influences the development of remedial alternatives in the FS, which in turn affects the data needs and scope of treatability studies and additional field investigations. The RI/FS should be viewed as a flexible process that can and should be tailored to specific circumstances and information needs of individual sites, not as a rigid approach that must be conducted identically at every site. Likewise, the human health evaluation process described here should be viewed the same way.

Two concepts are essential to the phased RI/FS approach. First, initial data collection efforts develop a general understanding of the site. Subsequent data collection effort focuses on filling previously unidentified gaps in the understanding of site characteristics and gathering information necessary to evaluate remedial alternatives. Second, key data needs should be identified as early in the process as possible to ensure that data collection is always directed toward providing information relevant to selection of a remedial action. In this way, the overall site characterization effort can be continually scoped to minimize the collection of unnecessary data and maximize data quality.

The RI/FS provides decision-makers with a technical evaluation of the threats posed at a site, a characterization of the potential routes of exposure, an assessment of remedial alternatives (including their relative advantages and

disadvantages), and an analysis of the trade-offs in selecting one alternative over another. EPA's interim final *Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA* (EPA 1988b) provides a detailed structure for the RI/FS. The RI/FS guidance provides further background that is helpful in understanding the place of the human health evaluation in the RI/FS process. The role that risk information plays in these stages of the RI/FS is described below; additional background can be found in the RI/FS guidance and in a summary of the guidance found in Chapter 2. Exhibit 1-1 illustrates the RI/FS process, showing where in the process risk information is gathered and analyzed.

1.1.1 PROJECT SCOPING

The purpose of project scoping is to define more specifically the appropriate type and extent of investigation and analysis that should be undertaken for a given site. During scoping, to assist in evaluating the possible impacts of releases from the site on human health and the environment, a conceptual model of the site should be established, considering in a qualitative manner the sources of contamination, potential pathways of exposure, and potential receptors. (Scoping is also the starting point for the risk assessment, during which exposure pathways are identified in the conceptual model for further investigation and quantification.)

PROJECT SCOPING

Program experience has shown that scoping is a very important step for the human health evaluation process, and both the health and environmental evaluation teams need to get involved in the RI/FS during the scoping stage. Planning for site data collection activities is necessary to focus the human health evaluation (and environmental evaluation) on the minimum amount of sampling information in order to meet time and budget constraints, while at the same time ensuring that enough information is gathered to assess risks adequately. (See Chapter 3 for information on planning the human health evaluation.)

The preliminary characterization during project scoping is initially developed with readily available information and is refined as additional data are collected. The main objectives of scoping are to identify the types of decisions that need to be made, to determine the types (including quantity and quality) of data needed, and to design efficient studies to collect these data. Potential site-specific modeling activities should be discussed at initial scoping meetings to ensure that modeling results will supplement the sampling data and effectively support risk assessment activities.

1.1.2 SITE CHARACTERIZATION (RI)

During site characterization, the sampling and analysis plan developed during project scoping is implemented and field data are collected and analyzed to determine the nature and extent of threats to human health and the environment posed by a site. The major components of site characterization are:

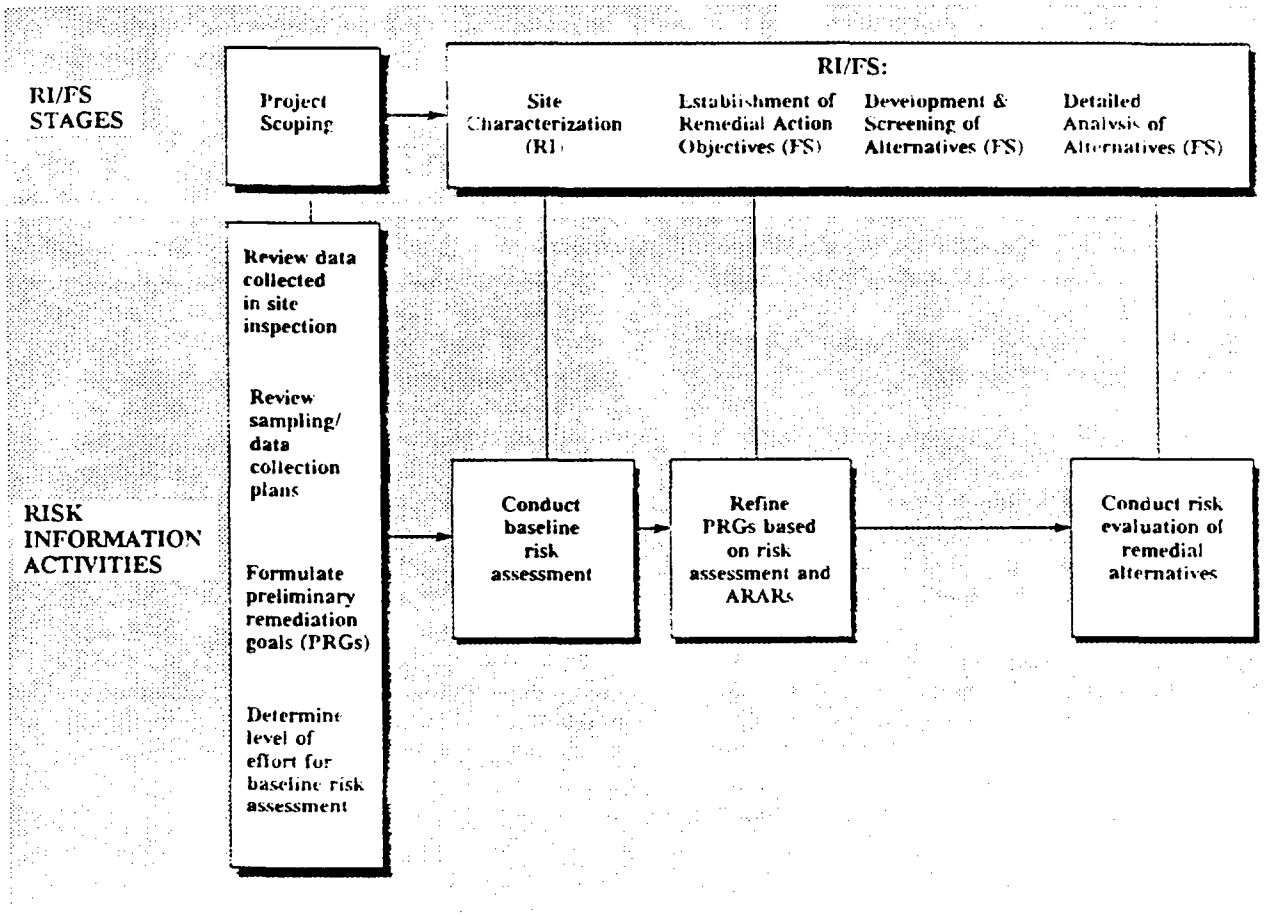
- collection and analysis of field data to characterize the site;
- development of a baseline risk assessment for both potential human health effects and potential environmental effects; and
- treatability studies, as appropriate.

Part of the human health evaluation, the baseline risk assessment (Part A of this manual) is an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action). The baseline risk assessment contributes to the site characterization and subsequent development, evaluation, and selection of appropriate response alternatives. The results of the baseline risk assessment are used to:

- help determine whether additional response action is necessary at the site;
- modify preliminary remediation goals;

EXHIBIT 1-1

RISK INFORMATION ACTIVITIES IN THE RI/FS PROCESS



- help support selection of the "no-action" remedial alternative, where appropriate; and

- document the magnitude of risk at a site, and the primary causes of that risk.

Baseline risk assessments are site-specific and therefore may vary in both detail and the extent to which qualitative and quantitative analyses are used, depending on the complexity and particular circumstances of the site, as well as the availability of applicable or relevant and appropriate requirements (ARARs) and other criteria, advisories, and guidance. After an initial planning stage (described more fully in Chapter 3), there are four steps in the baseline risk assessment process: data collection and analysis; exposure assessment; toxicity assessment; and risk characterization. Each step is described briefly below and presented in Exhibit 1-2.

Data collection and evaluation involves gathering and analyzing the site data relevant to the human health evaluation and identifying the substances present at the site that are the focus of the risk assessment process. (Chapters 4 and 5 address data collection and evaluation.)

An exposure assessment is conducted to estimate the magnitude of actual and/or potential human exposures, the frequency and duration of these exposures, and the pathways by which humans are potentially exposed. In the exposure assessment, reasonable maximum estimates of exposure are developed for both current and future land-use assumptions. Current exposure estimates are used to determine whether a threat exists based on existing exposure conditions at the site. Future exposure estimates are used to provide decision-makers with an understanding of potential future exposures and threats and include a qualitative estimate of the likelihood of such exposures occurring. Conducting an exposure assessment involves analyzing contaminant releases; identifying exposed populations; identifying all potential pathways of exposure; estimating exposure point concentrations for specific pathways, based both on environmental monitoring data and predictive chemical modeling results; and estimating contaminant intakes for specific pathways. The results of this assessment are pathway-specific intakes for current and future exposures to individual substances. (Chapter 6 addresses exposure assessment.)

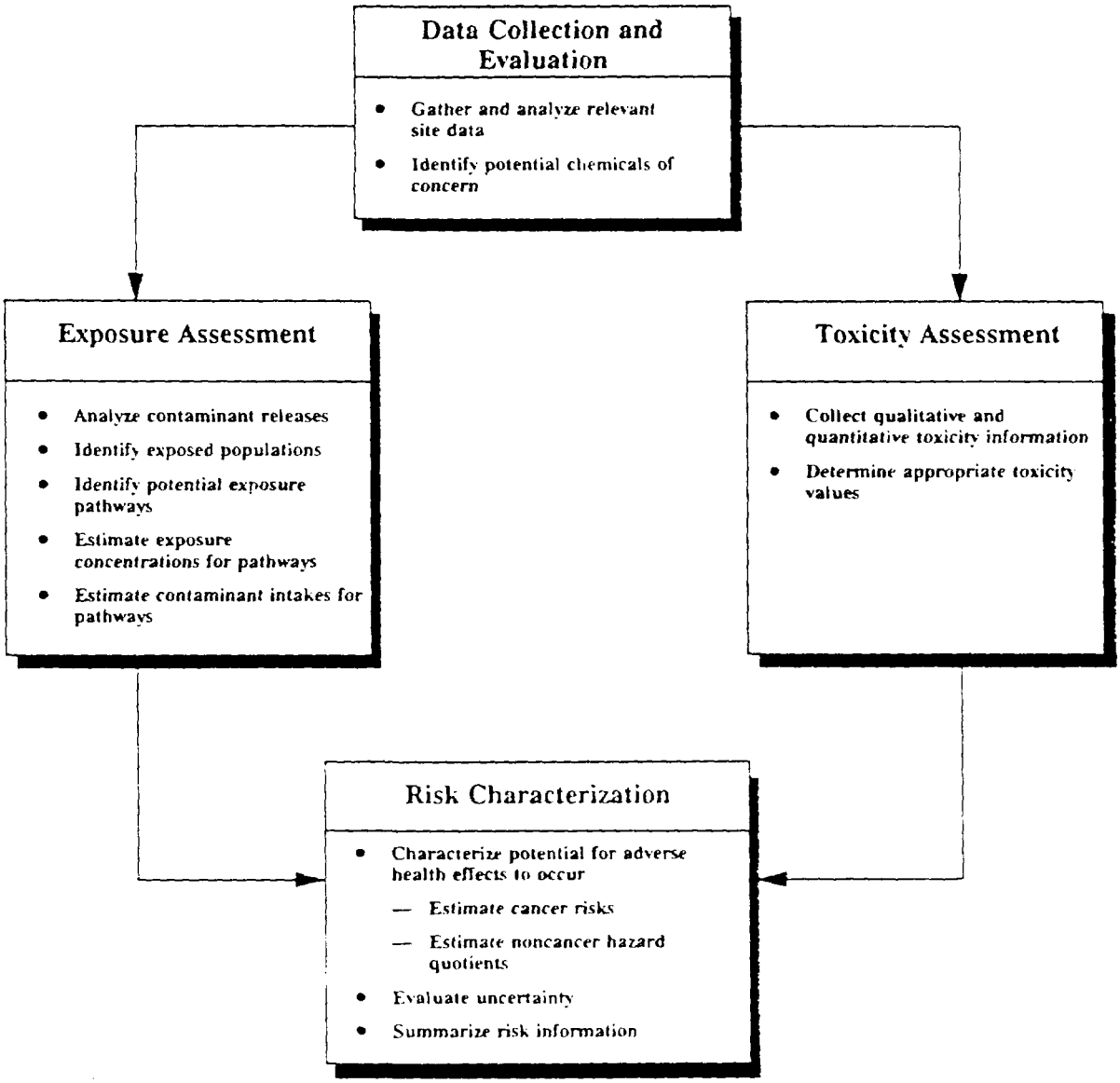
The toxicity assessment component of the Superfund baseline risk assessment considers: (1) the types of adverse health effects associated with chemical exposures; (2) the relationship between magnitude of exposure and adverse effects; and (3) related uncertainties such as the weight of evidence of a particular chemical's carcinogenicity in humans. Typically, the Superfund site risk assessments rely heavily on existing toxicity information developed on specific chemicals. Toxicity assessment for contaminants found at Superfund sites is generally accomplished in two steps: hazard identification and dose-response assessment. The first step, hazard identification, is the process of determining whether exposure to an agent can cause an increase in the incidence of an adverse health effect (e.g., cancer, birth defect). Hazard identification also involves characterizing the nature and strength of the evidence of causation. The second step, dose-response evaluation, is the process of quantitatively evaluating the toxicity information and characterizing the relationship between the dose of the contaminant administered or received and the incidence of adverse health effects in the exposed population. From this quantitative dose-response relationship, toxicity values are derived that can be used to estimate the incidence of adverse effects occurring in humans at different exposure levels. (Chapter 7 addresses toxicity assessment.)

The risk characterization summarizes and combines outputs of the exposure and toxicity assessments to characterize baseline risk, both in quantitative expressions and qualitative statements. During risk characterization, chemical-specific toxicity information is compared against both measured contaminant exposure levels and those levels predicted through fate and transport modeling to determine whether current or future levels at or near the site are of potential concern. (Chapter 8 addresses risk characterization.)

The level of effort required to conduct a baseline risk assessment depends largely on the complexity of the site. In situations where the results of the baseline risk assessment indicate that the site poses little or no threat to human health or the environment and that no further (or

EXHIBIT 1-2

PART A: BASELINE RISK ASSESSMENT



limited) action will be necessary, the FS should be scaled-down as appropriate.

The documents developed during site characterization include a brief preliminary site characterization summary and the draft RI report, which includes either the complete baseline risk assessment report or a summary of it. The preliminary site characterization summary may be used to assist in identification of ARARs and may provide the Agency for Toxic Substances and Disease Registry (ATSDR) with the data necessary to prepare its health assessment (different from baseline risk assessment or other EPA human health evaluation activities; see Chapter 2). The draft RI report is prepared after the completion of the baseline risk assessment, often along with the draft FS report.

1.1.3 FEASIBILITY STUDY

The purpose of the feasibility study is to provide the decision-maker with an assessment of remedial alternatives, including their relative strengths and weaknesses, and the trade-offs in selecting one alternative over another. The FS process involves developing a reasonable range of alternatives and analyzing these alternatives in detail using nine evaluation criteria. Because the RI and FS are conducted concurrently, this development and analysis of alternatives is an interactive process in which potential alternatives and remediation goals are continually refined as additional information from the RI becomes available.

Establishing protective remedial action objectives. The first step in the FS process involves developing remedial action objectives that address contaminants and media of concern, potential exposure pathways, and preliminary remediation goals. Under the proposed revised NCP and the interim RI/FS guidance, preliminary remediation goals typically are formulated first during project scoping or concurrent with initial RI activities (i.e., prior to completion of the baseline risk assessment). The preliminary remediation goals are therefore based initially on readily available chemical specific ARARs (e.g., maximum contaminant levels (MCLs) for drinking water). Preliminary remediation goals for individual substances are refined or confirmed at the conclusion of the baseline risk assessment (Part B of this manual addresses the refinement of preliminary remediation goals). These refined preliminary remediation goals are based both on risk assessment and on chemical-specific ARARs. Thus, they are intended to be protective and to comply with ARARs. The analytical approach used to develop these refined goals involves:

- identifying chemical-specific ARARs;
- identifying levels based on risk assessment where chemical-specific ARARs are not available or situations where multiple contaminants or multiple exposure pathways make ARARs not protective;
- identifying non-substance-specific goals for exposure pathways (if necessary); and
- determining a refined preliminary remediation goal that is protective of human health for all substance/exposure pathway combinations being addressed.

Development and screening of alternatives. Once remedial action objectives have been developed, general response actions, such as treatment, containment, excavation, pumping, or other actions that may be taken to satisfy those objectives should be developed. In the process of developing alternatives for remedial action at a site, two important activities take place. First, volumes or areas of waste or environmental media that need to be addressed by the remedial action are determined by information on the nature and extent of contamination, ARARs, chemical-specific environmental fate and toxicity information, and engineering analyses. Second, the remedial action alternatives and associated technologies are screened to identify those that would be effective for the contaminants and media of interest at the site. The information developed in these two activities is used in assembling technologies into alternatives for the site as a whole or for a specific operable unit.

The Superfund program has long permitted remedial actions to be staged through multiple operable units. Operable units are discrete actions that comprise incremental steps toward the final remedy. Operable units may be actions that completely address a geographical portion of a site

or a specific site problem (e.g., drums and tanks, contaminated ground water) or the entire site. Operable units include interim actions (e.g., pumping and treating of ground water to retard plume migration) that must be followed by subsequent actions to fully address the scope of the problem (e.g., final ground-water operable unit that defines the remediation goals and restoration timeframe). Such operable units may be taken in response to a pressing problem that will worsen if unaddressed, or because there is an opportunity to undertake a limited action that will achieve significant risk reduction quickly. The appropriateness of dividing remedial actions into operable units is determined by considering the interrelationship of site problems and the need or desire to initiate actions quickly. To the degree that site problems are interrelated, it may be most appropriate to address the problems together. However, where problems are reasonably separable, phased responses implemented through a sequence of operable units may promote more rapid risk reduction.

In situations where numerous potential remedial alternatives are initially developed, it may be necessary to screen the alternatives to narrow the list to be evaluated in detail. Such screening aids in streamlining the feasibility study while ensuring that the most promising alternatives are being considered.

Detailed analysis of alternatives. During the detailed analysis, each alternative is assessed against specific evaluation criteria and the results of this assessment arrayed such that comparisons between alternatives can be made and key trade-offs identified. Nine evaluation criteria, some of which are related to human health evaluation and risk, have been developed to address statutory requirements as well as additional technical and policy considerations that have proven to be important for selecting among remedial alternatives. These evaluation criteria, which are identified and discussed in the interim final RI/FS guidance, serve as the basis for conducting the detailed analyses during the FS and for subsequently selecting an appropriate remedial action. The nine evaluation criteria are as follows:

(1) overall protection of human health and the environment;

(2) compliance with ARARs (unless waiver applicable);

(3) long-term effectiveness and permanence;

(4) reduction of toxicity, mobility, or volume through the use of treatment;

(5) short-term effectiveness;

(6) implementability;

(7) cost;

(8) state acceptance; and

(9) community acceptance.

Risk information is required at the detailed analysis stage of the RI/FS so that each alternative can be evaluated in relation to the relevant NCP remedy selection criteria.

The detailed analysis must, according to the proposed NCP, include an evaluation of each alternative against the nine criteria. The first two criteria (i.e., overall protectiveness and compliance with ARARs) are threshold determinations and must be met before a remedy can be selected. Evaluation of the overall protectiveness of an alternative during the RI/FS should focus on how a specific alternative achieves protection over time and how site risks are reduced.

The next five criteria (numbers 3 through 7) are primary balancing criteria. The last two (numbers 8 and 9) are considered modifying criteria, and risk information does not play a direct role in the analysis of them. Of the five primary balancing criteria, risk information is of particular importance in the analysis of effectiveness and permanence. Analysis of long-term effectiveness and permanence involves an evaluation of the results of a remedial action in terms of residual risk at the site after response objectives have been met. A primary focus of this evaluation is the effectiveness of the controls that will be applied to manage risk posed by treatment residuals and/or any untreated wastes that may be left on the site, as well as the volume and nature of that material. It should also consider the potential impacts on human health and the environment should the remedy fail. An

evaluation of short-term effectiveness addresses the impacts of the alternative during the construction and implementation phase until remedial response objectives will be met. Under this criterion, alternatives should be evaluated with respect to the potential effects on human health and the environment during implementation of the remedial action and the length of time until protection is achieved.

1.2 OVERALL ORGANIZATION OF THE MANUAL

The next two chapters present additional background material for the human health evaluation process. Chapter 2 discusses statutes, regulations, guidance, and studies relevant to the Superfund human health evaluation. Chapter 3 discusses issues related to planning for the human health evaluation. The remainder of the manual is organized by the three parts of the human health evaluation process:

- the baseline risk assessment is covered in Part A of the manual (Chapters 4 through 10);
- refinement of preliminary remediation goals is covered in Part B of the manual (not included as part of this interim final version); and
- the risk evaluation of remedial alternatives is covered in Part C of the manual (not included as part of this interim final version).

Chapters 4 through 8 provide detailed technical guidance for conducting the steps of a baseline risk assessment, and Chapter 9 provides documentation and review guidelines. Chapter 10 contains additional guidance specific to baseline risk assessment for sites contaminated with radionuclides. Sample calculations, sample table formats, and references to other guidance are provided throughout the manual. All material is presented both in technical terms and in simpler text. It should be stressed that the manual is intended to be comprehensive and to provide guidance for more situations than usually are relevant to any single site. Risk assessors need not use those parts of the manual that do not apply to their site.

Each chapter in Part A includes a glossary of acronyms and definitions of commonly used terms. The manual also includes two appendices: Appendix A provides technical guidance for making absorption adjustments and Appendix B is an index.

ENDNOTES FOR CHAPTER 1

1. References made to CERCLA throughout this document should be interpreted as meaning "CERCLA, as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA)."

2. 40 CFR Part 300. Proposed revisions to the NCP were published on December 21, 1988 (53 Federal Register 51394).

3. The term "public health evaluation" was introduced in the previous risk assessment guidance (EPA 1986f) to describe the assessment of chemical releases from a site and the analysis of public health threats resulting from those releases, and Superfund site risk assessment studies often are referred to as public health evaluations, or PHEs. The term "PHE" should be replaced by whichever of the three parts of the revised human health evaluation process is appropriate: "baseline risk assessment," "documentation of preliminary remediation goals," or "risk evaluation of remedial alternatives."

4. Baseline risks are risks that might exist if no remediation or institutional controls were applied at a site.

5. Volume II of the Risk Assessment Guidance for Superfund is the Environmental Evaluation Manual (EPA 1989b), which provides guidance for the analysis of potential environmental (i.e., not human health) effects at sites.

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CHAPTER 2

STATUTES, REGULATIONS, GUIDANCE, AND STUDIES RELEVANT TO THE HUMAN HEALTH EVALUATION

This chapter briefly describes the statutes, regulations, guidance, and studies related to the human health evaluation process. The descriptions focus on aspects of these documents most relevant to human health evaluations and show how recent revisions to the documents bear upon the human health evaluation process. Section 2.1 describes the following documents that govern the human health evaluation:

- the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA, or Superfund) and the Superfund Amendments and Reauthorization Act of 1986 (SARA);
- the National Oil and Hazardous Substances Pollution Contingency Plan (National Contingency Plan, or NCP);
- *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (RI/FS guidance);
- *CERCLA Compliance with Other Laws Manual* (ARARs guidance); and
- *Superfund Exposure Assessment Manual* (SEAM).

Exhibit 2-1 shows the relationship of these statutes, regulations, and guidances governing human health evaluation. In addition, Section 2.2 identifies and briefly describes other Superfund studies related to, and sometimes confused with, the RI/FS human health evaluation. The types of studies discussed are:

- endangerment assessments;
- ATSDR health assessments; and
- ATSDR health studies.

2.1 STATUTES, REGULATIONS, AND GUIDANCE GOVERNING HUMAN HEALTH EVALUATION

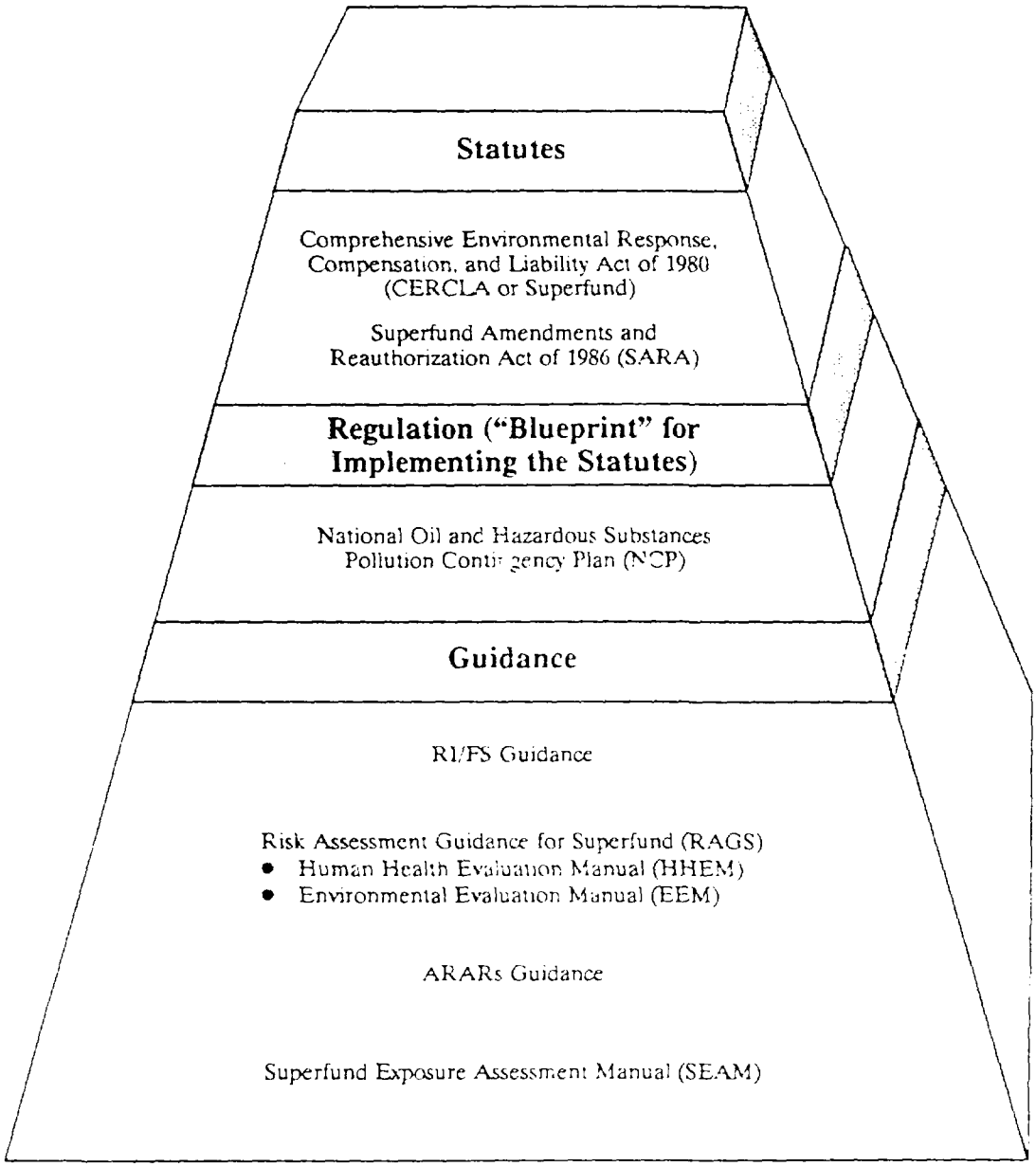
This section describes the major Superfund laws and program documents relevant to the human health evaluation process.

2.1.1 CERCLA AND SARA

In 1980, Congress enacted the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (42 U.S.C. 9601 et seq.), commonly called Superfund, in response to the dangers posed by sudden or otherwise uncontrolled releases of hazardous substances, pollutants, or contaminants into the environment. CERCLA authorized $1.6 billion over five years for a comprehensive program to clean up the

EXHIBIT 2-1

RELATIONSHIP OF DOCUMENTS GOVERNING HUMAN HEALTH EVALUATION



worst abandoned or inactive waste sites in the nation. CERCLA funds used to establish and administer the cleanup program are derived primarily from taxes on crude oil and 42 different commercial chemicals.

The reauthorization of CERCLA is known as the Superfund Amendments and Reauthorization Act (SARA), and was signed by the President on October 17, 1986. (All further references to CERCLA in this appendix should be interpreted as "CERCLA as amended by SARA.") These amendments provided $8.5 billion for the cleanup program and an additional $500 million for cleanup of leaks from underground storage tanks. Under SARA, Congress strengthened EPA's mandate to focus on permanent cleanups at Superfund sites, involve the public in decision processes at sites, and encourage states and federally recognized Indian tribes to actively participate as partners with EPA to address these sites. SARA expanded EPA's research, development (especially in the area of alternative technologies), and training responsibilities. SARA also strengthened EPA's enforcement authority. The changes to CERCLA sections 104 (Response Authorities) and 121 (Cleanup Standards) have the greatest impact on the RI/FS process.

Cleanup standards. Section 121 (Cleanup Standards) states a strong preference for remedies that are highly reliable and provide long-term protection. In addition to the requirement for remedies to be both protective of human health and the environment and cost-effective, other remedy selection considerations in section 121(b) include:

- a preference for remedial actions that employ (as a principal element of the action) treatment that permanently and significantly reduces the volume, toxicity, or mobility of hazardous substances, pollutants, and contaminants;
- offsite transport and disposal without treatment as the least favored alternative where practicable treatment technologies are available; and
- the need to assess the use of alternative treatment technologies or resource recovery technologies and use them to the maximum extent practicable.

Section 121(c) of CERCLA requires a periodic review of remedial actions, at least every five years after initiation, for as long as hazardous substances, pollutants, or contaminants that may pose a threat to human health or the environment remain at the site. If during a five-year review it is determined that the action no longer protects human health and the environment, further remedial actions will need to be considered.

Section 121(d)(2)(A) of CERCLA incorporates into law the CERCLA Compliance Policy, which specifies that Superfund remedial actions meet any federal standards, requirements, criteria, or limitations that are determined to be legally applicable or relevant and appropriate requirements (i.e., ARARs). Also included is the new provision that state ARARs must be met if they are more stringent than federal requirements. (Section 2.1.4 provides more detail on ARARs.)

Health-related authorities. Under CERCLA section 104(i)(6), the Agency for Toxic Substances and Disease Registry (ATSDR) is required to conduct a health assessment for every site included or proposed for inclusion on the National Priorities List. The ATSDR health assessment, which is fairly qualitative in nature, should be distinguished from the EPA human health evaluation, which is more quantitative. CERCLA section 104(i)(5)(F) states that:

> the term "health assessments" shall include preliminary assessments of the potential risk to human health posed by individual sites and facilities, based on such factors as the nature and extent of contamination, the existence of potential pathways of human exposure (including ground or surface water contamination, air emissions, and food chain contamination), the size and potential susceptibility of the community within the likely pathways of exposure, the comparison of expected human exposure levels to the short-term and long-term health effects associated with identified hazardous substances and any available recommended exposure or tolerance limits for such hazardous substances, and the comparison of existing morbidity and mortality data on

diseases that may be associated with the observed levels of exposure. The Administrator of ATSDR shall use appropriate data, risk assessments, risk evaluations and studies available from the Administrator of EPA.

There are purposeful differences between an ATSDR health assessment and traditional risk assessment. The health assessment is usually qualitative, site-specific, and focuses on medical and public health perspectives. Exposures to site contaminants are discussed in terms of especially sensitive populations, mechanisms of toxic chemical action, and possible disease outcomes. Risk assessment, the framework of the EPA human health evaluation, is a characterization of the probability of adverse effects from human exposures to environmental hazards. In this context, risk assessments differ from health assessments in that they are quantitative, chemical-oriented characterizations that use statistical and biological models to calculate numerical estimates of risk to health. However, both health assessments and risk assessments use data from human epidemiological investigations, when available, and when human toxicological data are unavailable, rely on the results of animal toxicology studies.

2.1.2 NATIONAL CONTINGENCY PLAN (NCP)

The National Contingency Plan provides the organizational structure and procedures for preparing for and responding to discharges of oil and releases of hazardous substances, pollutants, and contaminants. The NCP is required by section 105 of CERCLA and by section 311 of the Clean Water Act. The current NCP (EPA 1985) was published on November 20, 1985, and a significantly revised version (EPA 1988a) was proposed December 21, 1988 in response to SARA. The proposed NCP is organized into the following subparts:

- Subpart A -- Introduction
- Subpart B -- Responsibility and Organization for Response
- Subpart C -- Planning and Preparedness
- Subpart D -- Operational Response Phases for Oil Removal
- Subpart E -- Hazardous Substance Response
- Subpart F -- State Involvement in Hazardous Substance Response
- Subpart G -- Trustees for Natural Resources
- Subpart H -- Participation by Other Persons
- Subpart I -- Administrative Record for Selection of Response Action
- Subpart J -- Use of Dispersants and Other Chemicals

Subpart E, Hazardous Substance Response, contains a detailed plan covering the entire range of authorized activities involved in abating and remedying releases or threats of releases of hazardous substances, pollutants, and contaminants. It contains provisions for both removal and remedial response. The remedial response process set forth by the proposed NCP is a seven-step process, as described below. Risk information plays a role in each step.

Site discovery or notification. Releases of hazardous substances, pollutants, or contaminants identified by federal, state, or local government agencies or private parties are reported to the National Response Center or EPA. Upon discovery, such potential sites are screened to identify release situations warranting further remedial response consideration. These sites are entered into the CERCLA Information System (CERCLIS). This computerized system serves as a data base of site information and tracks the change in status of a site through the response process. Risk information is used to determine which substances are hazardous and, in some cases, the quantities that constitute a release that must be reported (i.e., a reportable quantity, or RQ, under CERCLA section 103(a)).

Preliminary assessment and site inspection (PA/SI). The preliminary assessment involves collection and review of all available information

and may include offsite reconnaissance to evaluate the source and nature of hazardous substances present and to identify the responsible party(ies). At the conclusion of the preliminary assessment, a site may be referred for further action, or a determination may be made that no further action is needed. Site inspections, which follow the preliminary assessment for sites needing further action, routinely include the collection of samples and are conducted to help determine the extent of the problem and to obtain information needed to determine whether a removal action is warranted. If, based on the site inspection, it appears likely that the site should be considered for inclusion on the National Priorities List (NPL), a listing site inspection (LSI) is conducted. The LSI is a more extensive investigation than the SI, and a main objective of the LSI is to collect sufficient data about a site to support Hazard Ranking System (HRS) scoring. One of the main objectives of the PA/SI is to collect risk-related information for sites so that the site can be scored using the HRS and priorities may be set for more detailed studies, such as the RI/FS.

Establishing priorities for remedial action. Sites are scored using the HRS, based on data from the PA/SI/LSI. The HRS scoring process is the primary mechanism for determining the sites to be included on the NPL and, therefore, the sites eligible for Superfund-financed remedial action. The HRS is a numerical scoring model that is based on many of the factors affecting risk at a site. A revised version of the HRS (EPA 1988b) was proposed December 23, 1988.

Remedial investigation/feasibility study (RI/FS). As described in Section 1.1, the RI/FS is the framework for determining appropriate remedial actions at Superfund sites. Although RI/FS activities technically are removal actions and therefore not restricted to sites on the NPL (see sections 101(23) and 104(b) of CERCLA), they most frequently are undertaken at NPL sites. Remedial investigations are conducted to characterize the contamination at the site and to obtain information needed to identify, evaluate, and select cleanup alternatives. The feasibility study includes an analysis of alternatives based on the nine NCP evaluation criteria. The human health evaluation described in this manual, and the environmental evaluation described elsewhere, are the guidance for developing risk information in the RI/FS.

Selection of remedy. The primary consideration in selecting a remedy is that it be protective of human health and the environment, by eliminating, reducing, or controlling risks posed through each pathway. Thus, the risk information developed in the RI/FS is a key input to remedy selection. The results of the RI/FS are reviewed to identify a preferred alternative, which is announced to the public in a Proposed Plan. Next, the lead agency reviews any resulting public comments on the Proposed Plan, consults with the support agencies to evaluate whether the preferred alternative is still the most appropriate, and then makes a final decision. A record of decision (ROD) is written to document the rationale for the selected remedy.

Remedial design/remedial action. The detailed design of the selected remedial action is developed and then implemented. The risk information developed previously in the RI/FS helps refine the remediation goals that the remedy will attain.

Five-year review. Section 121(c) of CERCLA requires a periodic review of remedial actions, at least every five years after initiation of such action, for as long as hazardous substances, pollutants, or contaminants that may pose a threat to human health or the environment remain at the site. If it is determined during a five-year review that the action no longer protects human health and the environment, further remedial actions will need to be considered.

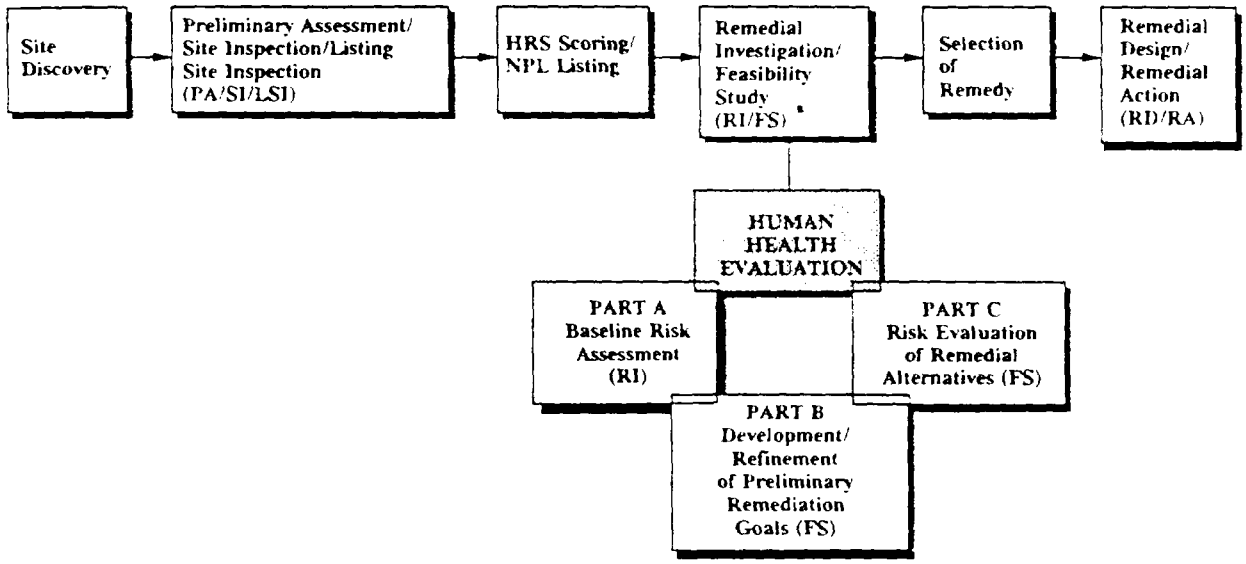
Exhibit 2-2 diagrams the general steps of the Superfund remedial process, indicating where in the process the various parts of the human health evaluation are conducted.

2.1.3 REMEDIAL INVESTIGATION/ FEASIBILITY STUDY GUIDANCE

EPA's interim final *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA 1988c) provides a detailed structure for conducting field studies to support remedial decisions and for identifying, evaluating, and selecting remedial action alternatives under CERCLA. This 1988 guidance document is a

EXHIBIT 2–2

ROLE OF THE HUMAN HEALTH EVALUATION IN THE SUPERFUND REMEDIAL PROCESS



* The RI/FS can be undertaken prior to NPL listing.

revision of two separate guidances for remedial investigations and for feasibility studies published in 1985. These guidances have been consolidated into a single document and revised to:

- reflect new emphasis and provisions of SARA;
- incorporate aspects of new or revised guidance related to RI/FSs;
- incorporate management initiatives designed to streamline the RI/FS process; and
- reflect experience gained from previous RI/FS projects.

The RI/FS consists of the following general steps:

- project scoping (during the RI);
- site characterization (RI);
- establishment of remedial action objectives (FS);
- development and screening of alternatives (FS); and
- detailed analysis of alternatives (FS).

Because Section 1.1 describes each of these steps, focusing on the role that risk information plays in the RI/FS, a discussion of the steps is not repeated here. The RI/FS guidance provides the context into which the human health evaluation fits and should be used in conjunction with this manual.

2.1.4 ARARS GUIDANCE

The interim final *CERCLA Compliance with Other Laws Manual* (EPA 1988d; EPA 1989a), or ARARs guidance, was developed to assist in the selection of onsite remedial actions that meet the applicable or relevant and appropriate requirements (ARARs) of the Resource Conservation and Recovery Act (RCRA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Clean Air Act (CAA), and other federal and state environmental laws, as required by CERCLA section 121. Part I of the manual discusses the overall procedures for identifying ARARs and provides guidance on the interpretation and analysis of RCRA requirements. Specifically:

- Chapter 1 defines "applicable" and "relevant and appropriate," provides matrices listing potential chemical-specific, location-specific, and action-specific requirements from RCRA, CWA, and SDWA, and provides general procedures for identifying and analyzing requirements;
- Chapter 2 discusses special issues of interpretation and analysis involving RCRA requirements, and provides guidance on when RCRA requirements will be ARARs for CERCLA remedial actions;
- Chapter 3 provides guidance for compliance with CWA substantive (for onsite and offsite actions) and administrative (for offsite actions) requirements for direct discharges, indirect discharges, and dredge and fill activities;
- Chapter 4 provides guidance for compliance with requirements of the SDWA that may be applicable or relevant and appropriate to CERCLA sites; and
- Chapter 5 provides guidance on consistency with policies for ground-water protection.

The manual also contains a hypothetical scenario illustrating how ARARs are identified and used, and an appendix summarizing the provisions of RCRA, CWA, and SDWA.

Part II of the ARARs guidance covers the Clean Air Act, other federal statutes, and state requirements. Specifically:

- Chapter 1 provides an introduction to Part II of the guidance, and also includes extensive summary tables;

- Chapter 2 describes Clean Air Act requirements and related RCRA and state requirements;
- Chapters 3 and 4 provide guidance for compliance with several other federal statutes;
- Chapter 5 discusses potential ARARs for sites contaminated with radioactive substances;
- Chapter 6 addresses requirements specific to mining, milling, or smelting sites; and
- Chapter 7 provides guidance on identifying and complying with state ARARs.

2.1.5 SUPERFUND EXPOSURE ASSESSMENT MANUAL

The *Superfund Exposure Assessment Manual* (EPA 1988e), which was developed by the Superfund program specifically as a companion document to the original *Superfund Public Health Evaluation Manual* (EPA 1986), provides RPMs and regional risk assessors with the guidance necessary to conduct exposure assessments that meet the needs of the Superfund human health risk evaluation process. Specifically, the manual:

- provides an overall description of the integrated exposure assessment as it is applied to uncontrolled hazardous waste sites; and
- serves as a source of reference concerning the use of estimation procedures and computer modeling techniques for the analysis of uncontrolled sites.

The analytical process outlined in the *Superfund Exposure Assessment Manual* provides a framework for the assessment of exposure to contaminants at or migrating from uncontrolled hazardous waste sites. The application of both monitoring and modeling procedures to the exposure assessment process is outlined in the manual. This process considers all contaminant releases and exposure routes and assures that an adequate level of analytical detail is applied to support the human health risk assessment process.

The exposure assessment process described in the *Superfund Exposure Assessment Manual* is structured in five segments:

(1) analysis of contaminant releases from a subject site into environmental media;

(2) evaluation of the transport and environmental fate of the contaminants released;

(3) identification, enumeration, and characterization of potentially exposed populations;

(4) integrated exposure analysis; and

(5) uncertainty analysis.

Two recent publications from EPA's Office of Research and Development, the *Exposure Factors Handbook* (EPA 1989b) and the *Exposure Assessment Methods Handbook* (EPA 1989c), provide useful information to supplement the *Superfund Exposure Assessment Manual*. All three of these key exposure assessment references should be used in conjunction with Chapter 6 of this manual.

2.2 RELATED SUPERFUND STUDIES

This section identifies and briefly describes other Superfund studies related to, and sometimes confused with, the RI/FS human health evaluation. It contrasts the objectives and methods and clarifies the relationships of these other studies with RI/FS health risk assessments. The types of studies discussed are endangerment assessments, ATSDR health assessments, and ATSDR health studies.

2.2.1 ENDANGERMENT ASSESSMENTS

Before taking enforcement action against parties responsible for a hazardous waste site, EPA must determine that an imminent and substantial endangerment to public health or the

environment exists as a result of the site. Such a legal determination is called an endangerment assessment. For remedial sites, the process for analyzing whether there may be an endangerment is described in this *Human Health Evaluation Manual* and its companion *Environmental Evaluation Manual*. In the past, an endangerment assessment often was prepared as a study separate from the baseline risk assessment. With the passage of SARA and changes in Agency practice, the need to perform a detailed endangerment assessment as a separate effort from the baseline risk assessment has been eliminated.

For administrative orders requiring a remedial design or remedial action, endangerment assessment determinations are now based on information developed in the site baseline risk assessment. Elements included in the baseline risk assessment conducted at a Superfund site during the RI/FS process fully satisfy the informational requirements of the endangerment assessment. These elements include the following:

- identification of the hazardous wastes or hazardous substances present in environmental media;
- assessment of exposure, including a characterization of the environmental fate and transport mechanisms for the hazardous wastes and substances present, and of exposure pathways;
- assessment of the toxicity of the hazardous wastes or substances present;
- characterization of human health risks; and
- characterization of the impacts and/or risks to the environment.

The human health and environmental evaluations that are part of the RI/FS are conducted for purposes of determining the baseline risks posed by the site, and for ensuring that the selected remedy will be protective of human health and the environment. The endangerment assessment is used to support litigation by determining that an imminent and substantial endangerment exists. Information presented in the human health and environmental evaluations is basic to the legal determination of endangerment.

In 1985, EPA produced a draft manual specifically written for endangerment assessment, the *Endangerment Assessment Handbook*. EPA has determined that a guidance separate from the *Risk Assessment Guidance for Superfund* (*Human Health Evaluation Manual* and *Environmental Evaluation Manual*) is not required for endangerment assessment; therefore, the *Endangerment Assessment Handbook* will not be made final and should no longer be used.

2.2.2 ATSDR HEALTH ASSESSMENTS

CERCLA section 104(i), as amended, requires the Agency for Toxic Substances and Disease Registry (ATSDR) to conduct health assessments for all sites listed or proposed to be listed on the NPL. A health assessment includes a preliminary assessment of the potential threats that individual sites and facilities pose to human health. The health assessment is required to be completed "to the maximum extent practicable" before completion of the RI/FS. ATSDR personnel, state personnel (through cooperative agreements), or contractors follow six basic steps, which are based on the same general risk assessment framework as the EPA human health evaluation:

(1) evaluate information on the site's physical, geographical, historical, and operational setting, assess the demographics of nearby populations, and identify health concerns of the affected community(ies);

(2) determine contaminants of concern associated with the site;

(3) identify and evaluate environmental pathways;

(4) identify and evaluate human exposure pathways;

(5) identify and evaluate public health implications based on available medical and toxicological information; and

(6) develop conclusions concerning the health threat posed by the site and make

recommendations regarding further public health activities.

The purpose of the ATSDR health assessment is to assist in the evaluation of data and information on the release of toxic substances into the environment in order to assess any current or future impact on public health, develop health advisories or other health-related recommendations, and identify studies or actions needed to evaluate and prevent human health effects. Health assessments are intended to help public health and regulatory officials determine if actions should be taken to reduce human exposure to hazardous substances and to recommend whether additional information on human exposure and associated risks is needed. Health assessments also are written for the benefit of the informed community associated with a site, which could include citizen groups, local leaders, and health professionals.

Several important differences exist between EPA human health evaluations and ATSDR health assessments. EPA human health evaluations include quantitative, substance-specific estimates of the risk that a site poses to human health. These estimates depend on statistical and biological models that use data from human epidemiologic investigations and animal toxicity studies. The information generated from a human health evaluation is used in risk management decisions to establish cleanup levels and select a remedial alternative.

ATSDR health assessments, although they may employ quantitative data, are more qualitative in nature. They focus not only on the possible health threats posed by chemical contaminants attributable to a site, but consider all health threats, both chemical and physical, to which residents near a site may be subjected. Health assessments focus on the medical and public health concerns associated with exposures at a site and discuss especially sensitive populations, toxic mechanisms, and possible disease outcomes. EPA considers the information in a health assessment along with the results of the baseline risk assessment to give a complete picture of health threats. Local health professionals and residents use the information to understand the potential health threats posed by specific waste sites. Health assessments may lead to pilot health effects studies, epidemiologic studies, or establishment of exposure or disease registries.

EPA's *Guidance for Coordinating ATSDR Health Assessment Activities with the Superfund Remedial Process* (EPA 1987) provides information to EPA and ATSDR managers for use in coordinating human health evaluation activities. (Section 2.1, in its discussion of CERCLA, provides further information on the statutory basis of ATSDR health assessments.)

2.2.3 ATSDR HEALTH STUDIES

After conducting a health assessment, ATSDR may determine that additional health effects information is needed at a site and, as a result, may undertake a pilot study, a full-scale epidemiological study, or a disease registry. Three types of pilot studies are predominant:

(1) a symptom/disease prevalence study consisting of a measurement of self-reported disease occurrence, which may be validated through medical records if they are available;

(2) a human exposure study consisting of biological sampling of persons who have a potentially high likelihood of exposure to determine if actual exposure can be verified; and

(3) a cluster investigation study consisting of an investigation of putative disease clusters to determine if the cases of a disease are excessively high in the concerned community.

A full-scale epidemiological study is an analytic investigation that evaluates the possible causal relationships between exposure to hazardous substances and disease outcome by testing a scientific hypothesis. Such an epidemiological study is usually not undertaken unless a pilot study reveals widespread exposure or increased prevalence of disease.

ATSDR, in cooperation with the states, also may choose to follow up the results of a health assessment by establishing and maintaining national registries of persons exposed to hazardous substances and persons with serious diseases or

illness. A registry is a system for collecting and maintaining, in a structured record, information on specific persons from a defined population. The purpose of a registry of persons exposed to hazardous substances is to facilitate development of new scientific knowledge through identification and subsequent follow-up of persons exposed to a defined substance at selected sites.

Besides identifying and tracking of exposed persons, a registry also is used to coordinate the clinical and research activities that involve the registrants. Registries serve an important role in assuring the uniformity and quality of the collected data and ensuring that data collection is not duplicative, thereby reducing the overall burden to exposed or potentially exposed persons.

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CHAPTER 3

GETTING STARTED: PLANNING FOR THE HUMAN HEALTH EVALUATION IN THE RI/FS

This chapter discusses issues related to planning the human health evaluation conducted during the RI/FS. It presents the goals of the RI/FS process as a whole and the human health evaluation in particular (Sections 3.1 and 3.2). It next discusses the way in which a site that is divided into operable units should be treated in the human health evaluation (Section 3.3). RI/FS scoping is discussed in Section 3.4, and Section 3.5 addresses the level of effort and detail necessary for a human health evaluation.

3.1 GOAL OF THE RI/FS

The goal of the RI/FS is to gather information sufficient to support an informed risk management decision regarding which remedy appears to be most appropriate for a given site. The RI/FS provides the context for all site characterization activity, including the human health evaluation. To attain this goal efficiently, EPA must identify and characterize hazards in a way that will contribute directly to the selection of an appropriate remedy. Program experience has shown that Superfund sites are complex, and are characterized by heterogeneous wastes, extreme variability in contamination levels, and a variety of environmental settings and potential exposure pathways. Consequently, complete characterization of a site during the RI/FS, in the sense of eliminating uncertainty, is not feasible, cost-effective, or necessary for selection of appropriate remedies. This view has motivated the "streamlined approach" EPA is taking to help accomplish the goal of completing an RI/FS in 18 months at a cost of $750,000 per operable unit and $1.1 million per site. The streamlined approach recognizes that the elimination of all uncertainties is not possible or necessary and instead strives only for sufficient data to generally characterize a site and support remedy selection. The resulting remedies are flexible and incorporate specific contingencies to respond to new information discovered during remedial action and follow-up.

3.2 GOAL OF THE RI/FS HUMAN HEALTH EVALUATION

As part of the effort to streamline the process and reduce the cost and time required to conduct the RI/FS, the Superfund human health evaluation needs to focus on providing information necessary to justify action at a site and to select the best remedy for the site. This should include characterizing the contaminants, the potential exposures, and the potentially exposed population sufficiently to determine what risks need to be reduced or eliminated and what exposures need to be prevented. It is important to recognize that information should be developed only to help EPA determine what actions are necessary to reduce risks, and not to fully characterize site risks or eliminate all uncertainty from the analysis.

In a logical extension of this view, EPA has made a policy decision to use, wherever appropriate, standardized assumptions, equations, and values in the human health evaluation to achieve the goal of streamlined assessment. This approach has the added benefit of making human

health evaluation easier to review, easier to understand, and more consistent from site to site. Developing unique exposure assumptions or non-standard methods of risk assessment should not be necessary for most sites. Where justified by site-specific data or by changes in knowledge over time, however, non-standard methods and assumptions may be used.

3.3 OPERABLE UNITS

Current practice in designing remedies for Superfund sites often divides sites into operable units that address discrete aspects of the site (e.g., source control, ground-water remediation) or different geographic portions of the site. The NCP defines operable unit as "a discrete action that comprises an incremental step toward comprehensively addressing site problems." RI/FSs may be conducted for the entire site and operable units broken out during or after the feasibility study, or operable units may be treated individually from the start, with focused RI/FSs conducted for each operable unit. The best way to address the risks of the operable unit will depend on the needs of the site.

The human health evaluation should focus on the subject of the RI/FS, whether that is an operable unit or the site as a whole. The baseline risk assessment and other risk information gathered will provide the justification for taking the action for the operable unit. At the same time, personnel involved in conducting the human health evaluation for a focused RI/FS must be mindful of other potential exposure pathways, and other actions that are being contemplated for the site to address other potential exposures. Risk assessors should foresee that exposure pathways outside the scope of the focused RI/FS may ultimately be combined with exposure pathways that are directly addressed by the focused RI/FS. Considering risks from all related operable units should prevent the unexpected discovery of high multiple pathway risks during the human health evaluation for the last operable unit. Consider, for example, a site that will be addressed in two operable units: a surface soil cleanup at the contamination source and a separate ground-water cleanup. Risks associated with residuals from the soil cleanup and the ground-water cleanup may need to be considered as a cumulative total if there is the potential for exposure to both media at the same time.

3.4 RI/FS SCOPING

Planning the human health evaluation prior to beginning the detailed analysis is an essential step in the process. The RPM must make up-front decisions about, for example, the scope of the baseline risk assessment, the appropriate level of detail and documentation, trade-offs between depth and breadth in the analysis, and the staff and monetary resources to commit.

Scoping is the initial planning phase of the RI/FS process, and many of the planning steps begun here are continued and refined in later phases. Scoping activities typically begin with the collection of existing site data, including data from previous investigations such as the preliminary assessment and site inspection. On the basis of this information, site management planning is undertaken to identify probable boundaries of the study area, to identify likely remedial action objectives and whether interim actions may be necessary or appropriate, and to establish whether the site may best be remedied as one site or as several separate operable units. Once an overall management strategy is agreed upon, the RI/FS for a specific project or the site as a whole is planned.

The development of remedial alternatives usually begins during or soon after scoping, when likely response scenarios may first be identified. The development of alternatives requires:

- identifying remedial action objectives;
- identifying potential treatment, resource recovery, and containment technologies that will satisfy these objectives; and
- screening the technologies based on their effectiveness, implementability, and cost.

Remedial alternatives may be developed to address a contaminated medium, a specific area of the site, or the entire site. Alternative remedial actions for specific media and site areas either can be carried through the FS process separately or combined into comprehensive alternatives for the

entire site. The approach is flexible to allow alternatives to be considered in combination at various points in the process. The RI/FS guidance discusses planning in greater detail.

3.5 LEVEL OF EFFORT/LEVEL OF DETAIL OF THE HUMAN HEALTH EVALUATION

An important part of scoping is determining the appropriate level of effort/level of detail necessary for the human health evaluation. Human health evaluation can be thought of as spanning a continuum of complexity, detail, and level of effort, just as sites vary in conditions and complexity. Some of the site-specific factors affecting level of effort that the RPM must consider include the following:

- number and identity of chemicals present;
- availability of ARARs and/or applicable toxicity data;
- number and complexity of exposure pathways (including complexity of release sources and transport media), and the need for environmental fate and transport modeling to supplement monitoring data;
- necessity for precision of the results, which in turn depends on site conditions such as the extent of contaminant migration, characteristics of potentially exposed populations, and enforcement considerations (additional quantification may be warranted for some enforcement sites); and
- quality and quantity of available monitoring data.

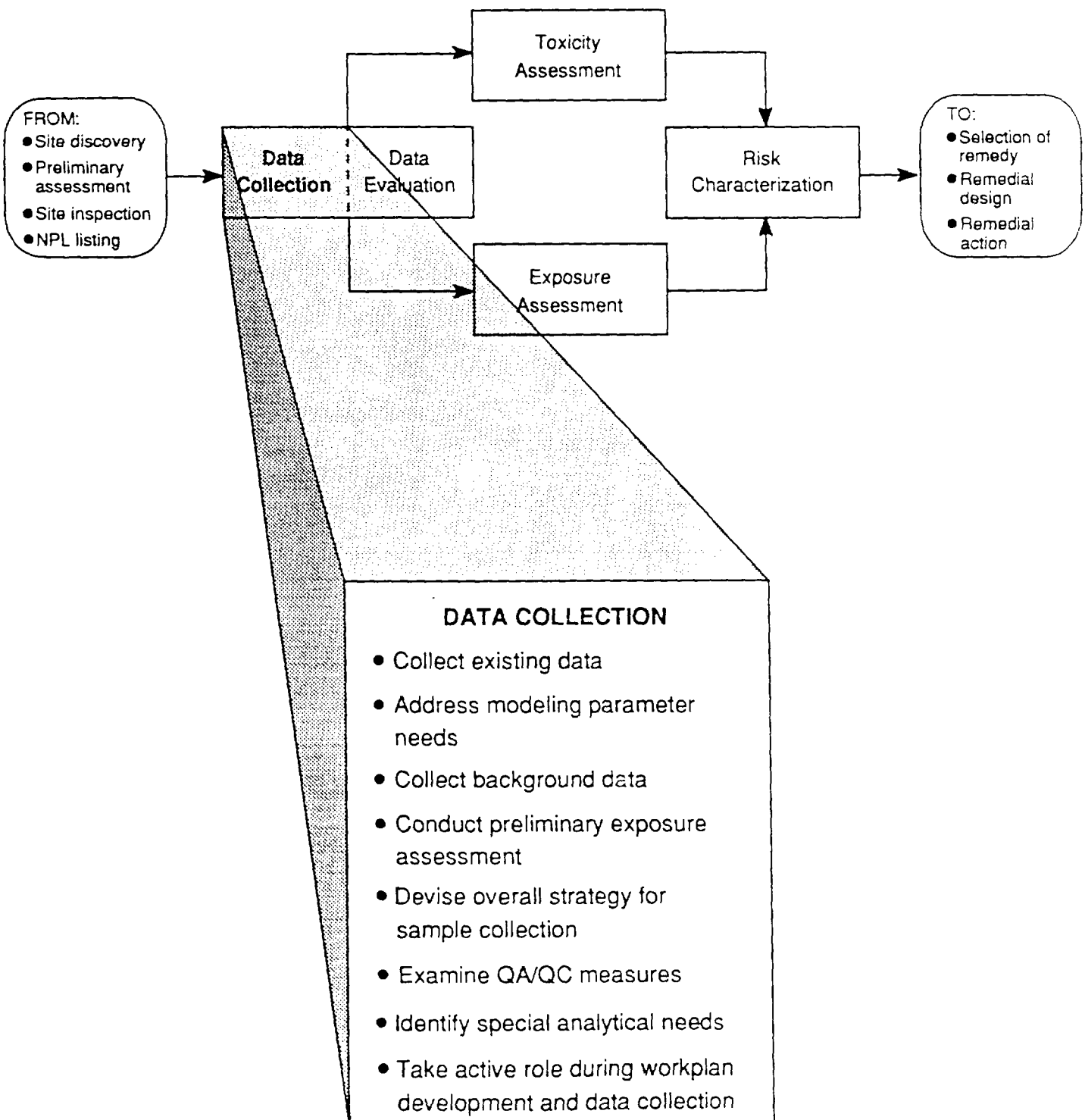
This manual is written to address the most complex sites, and as a result not all of the steps and procedures of the Superfund human health evaluation process described in this manual apply to all remedial sites. For example, Section 6.6 provides procedures and equations for estimating chemical intakes through numerous exposure routes, although for many sites, much of this information will not apply (e.g., the exposure route does not exist or is determined to be relatively unimportant). This manual establishes a generic framework that is broadly applicable across sites, and it provides specific procedures that cover a range of sites or situations that may or may not be appropriate for any individual site. As a consequence of attempting to cover the wide variety of Superfund site conditions, some of the process components, steps, and techniques described in the manual do not apply to some sites. In addition, most of the components can vary greatly in level of detail. Obviously, determining which elements of the process are necessary, which are desirable, and which are extraneous is a key decision for each site. All components should not be forced into the assessment of a site, and the evaluation should be limited to the complexity and level of detail necessary to adequately assess risks for the purposes described in Sections 3.1 and 3.2.

Planning related to the collection and analysis of chemical data is perhaps the most important planning step. Early coordination among the risk assessors, the remainder of the RI/FS team, representatives of other agencies involved in the risk assessment or related studies (e.g., ATSDR, natural resource trustees such as the Department of the Interior, state agencies), and the RPM is essential and preferably should occur during the scoping stage of the RI/FS. Detailed guidance on planning related to collection and analysis of chemical data is given in Chapter 4 of this manual.

ENDNOTE FOR CHAPTER 3

1. All site monitoring data must be subjected to appropriate quality assurance/quality control programs. Lack of acceptable data may limit by necessity the amount of data available for the human health evaluation, and therefore may limit the scope of the evaluation. Acceptability is determined by whether data meet the appropriate data quality objectives (see Section 4.1.2).

CHAPTER 4
DATA COLLECTION



CHAPTER 4

DATA COLLECTION

This chapter discusses procedures for acquiring reliable chemical release and exposure data for quantitative human health risk assessment at hazardous waste sites.[1] The chapter is intended to be a limited discussion of important sampling considerations with respect to risk assessment; it is not intended to be a complete guide on how to collect data or design sampling plans.

Following a general background section (Section 4.1), this chapter addresses the following eight important areas:

(1) review of available site information (Section 4.2);

(2) consideration of modeling parameter needs (Section 4.3);

(3) definition of background sampling needs (Section 4.4);

(4) preliminary identification of potential human exposure (Section 4.5);

(5) development of an overall strategy for sample collection (Section 4.6);

(6) definition of required QA/QC measures (Section 4.7);

(7) evaluation of the need for Special Analytical Services (Section 4.8); and

(8) activities during workplan development and data collection (Section 4.9).

4.1 BACKGROUND INFORMATION USEFUL FOR DATA COLLECTION

This section provides background information on the types of data needed for risk assessment, overall data needs of the RI/FS, reasons and steps for identifying risk assessment data needs early, use of the *Data Quality Objectives for Remedial Response Activities* (EPA 1987a,b, hereafter referred to as the DQO guidance), and other data concerns.

4.1.1 TYPES OF DATA

In general, the types of site data needed for a baseline risk assessment include the following:

- contaminant identities;

ACRONYMS FOR CHAPTER 4

CLP = Contract Laboratory Program
DQO = Data Quality Objectives
FIT = Field Investigation Team
FSP = Field Sampling Plan
HRS = Hazard Ranking System
IDL = Instrument Detection Limit
MDL = Method Detection Limit
PA/SI = Preliminary Assessment/Site Inspection
QA/QC = Quality Assurance/Quality Control
QAPjP = Quality Assurance Project Plan
RAS = Routine Analytical Services
RI/FS = Remedial Investigation/Feasibility Study
SAP = Sampling and Analysis Plan
SAS = Special Analytical Services
SMO = Sample Management Office
SOW = Statement of Work
TAL = Target Analyte List
TCL = Target Compound List
TIC = Tentatively Identified Compound

DEFINITIONS FOR CHAPTER 4

Analytes. The chemicals for which a sample is analyzed.

Anthropogenic Background Levels. Concentrations of chemicals that are present in the environment due to human-made, non-site sources (e.g., industry, automobiles).

Contract Laboratory Program (CLP). Analytical program developed for Superfund waste site samples to fill the need for legally defensible analytical results supported by a high level of quality assurance and documentation.

Data Quality Objectives (DQOs). Qualitative and quantitative statements to ensure that data of known and documented quality are obtained during an RI/FS to support an Agency decision.

Field Sampling Plan (FSP). Provides guidance for all field work by defining in detail the sampling and data gathering methods to be used on a project.

Naturally Occurring Background Levels. Ambient concentrations of chemicals that are present in the environment and have not been influenced by humans (e.g., aluminum, manganese).

Quality Assurance Project Plan (QAPjP). Describes the policy, organization, functional activities, and quality assurance and quality control protocols necessary to achieve DQOs dictated by the intended use of the data (RI/FS Guidance).

Routine Analytical Services (RAS). The set of CLP analytical protocols that are used to analyze most Superfund site samples. These protocols are provided in the EPA Statements of Work for the CLP (SOW for Inorganics, SOW for Organics) and must be followed by every CLP laboratory.

Sampling and Analysis Plan (SAP). Consists of a Quality Assurance Project Plan (QAPjP) and a Field Sampling Plan (FSP).

Sample Management Office (SMO). EPA contractor providing management, operational, and administrative support to the CLP to facilitate optimal use of the program.

Special Analytical Services (SAS). Non-standardized analyses conducted under the CLP to meet user requirements that cannot be met using RAS, such as shorter analytical turnaround time, lower detection limits, and analysis of non-standard matrices or non-TCL compounds.

Statement of Work (SOW) for the CLP. A document that specifies the instrumentation, sample handling procedures, analytical parameters and procedures, required quantitation limits, quality control requirements, and report format to be used by CLP laboratories. The SOW also contains the TAL and TCL.

Target Analyte List (TAL). Developed by EPA for Superfund site sample analyses. The TAL is a list of 23 metals plus total cyanide routinely analyzed using RAS.

Target Compound List (TCL). Developed by EPA for Superfund site sample analyses. The TCL is a list of analytes (34 volatile organic chemicals, 65 semivolatile organic chemicals, 19 pesticides, 7 polychlorinated biphenyls, 23 metals, and total cyanide) routinely analyzed using RAS.

- contaminant concentrations in the key sources and media of interest;
- characteristics of sources, especially information related to release potential; and
- characteristics of the environmental setting that may affect the fate, transport, and persistence of the contaminants.

Most of these data are obtained during the course of a remedial investigation/feasibility study (RI/FS). Other sources of information, such as preliminary assessment/site inspection (PA/SI) reports, also may be available.

4.1.2 DATA NEEDS AND THE RI/FS

The RI/FS has four primary data collection components:

(1) characterization of site conditions;

(2) determination of the nature of the wastes;

(3) risk assessment; and

(4) treatability testing.

The site and waste characterization components of the RI/FS are intended to determine characteristics of the site (e.g., ground-water movement, surface water and soil characteristics) and the nature and extent of contamination through sampling and analysis of sources and potentially contaminated media. Quantitative risk assessment, like site characterization, requires data on concentrations of contaminants in each of the source areas and media of concern. Risk assessment also requires information on other variables necessary for evaluating the fate, transport, and persistence of contaminants and estimating current and potential human exposure to these contaminants. Additional data might be required for environmental risk assessments (see EPA 1989a).

Data also are collected during the RI/FS to support the design of remedial alternatives. As discussed in the DQO guidance (EPA 1987a,b), such data include results of analyses of contaminated media "before and after" bench-scale treatability tests. This information usually is not appropriate for use in a baseline risk assessment because these media typically are assessed only for a few individual parameters potentially affected by the treatment being tested. Also, initial treatability testing may involve only a screening analysis that generally is not sensitive enough and does not have sufficient quality assurance/quality control (QA/QC) procedures for use in quantitative risk assessment.

4.1.3 EARLY IDENTIFICATION OF DATA NEEDS

Because the RI/FS and other site studies serve a number of different purposes (e.g., site and waste characterization, design of remedial alternatives), only a subset of this information generally is useful for risk assessment. To ensure that all risk assessment data needs will be met, it is important to identify those needs early in the RI/FS planning for a site. The earlier the requirements are identified, the better the chances are of developing an RI/FS that meets the risk assessment data collection needs.

One of the earliest stages of the RI/FS at which risk assessment data needs can be addressed is the site scoping meeting. As discussed in the *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA 1988a, hereafter referred to as RI/FS guidance), the scoping meeting is part of the initial planning phase of site remediation. It is at this meeting that the data needs of each of the RI/FS components (e.g., site and waste characterization) are addressed together. Scoping meeting attendees include the RPM, contractors conducting the RI/FS (including the baseline risk assessment), onsite personnel (e.g., for construction), and natural resource trustees (e.g., Department of Interior). The scoping meeting allows development of a comprehensive sampling and analysis plan (SAP) that will satisfy the needs of each RI/FS component while helping to ensure that time and budget constraints are met. Thus, in addition to aiding the effort to meet the risk assessment data needs, this meeting can help integrate these needs with other objectives of the RI/FS and thereby help make maximum use of available resources and avoid duplication of effort.

During scoping activities, the risk assessor should identify, at least in preliminary fashion, the type and duration of possible exposures (e.g., chronic, intermittent), potential exposure routes (e.g., ingestion of fish, ingestion of drinking water, inhalation of dust), and key exposure points (e.g., municipal wells, recreation areas) for each medium. The relative importance of the potential exposure routes and exposure points in determining risks should be discussed, as should the consequences of not studying them adequately. Section 4.5 and Chapter 6 provide guidance for identifying exposure pathways that may exist at hazardous waste sites. If potential exposure pathways are identified early in the RI/FS process, it will be easier to reach a decision on the number, type, and location of samples needed to assess exposure.

During the planning stages of the RI/FS, the risk assessor also should determine if non-routine (i.e., lower) quantitation limits are needed to adequately characterize risks at a site. Special Analytical Services (SAS) of the EPA Contract

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(4) treatability testing.

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During the planning stages of the RI/FS, the risk assessor also should determine if non-routine (i.e., lower) quantitation limits are needed to adequately characterize risks at a site. Special Analytical Services (SAS) of the EPA Contract

Laboratory Program (CLP) may be needed to achieve such lower quantitation limits. (See Section 4.8 for additional information concerning quantitation limits.)

4.1.4 USE OF THE DATA QUALITY OBJECTIVES (DQO) GUIDANCE

The DQO guidance (EPA 1987a,b) provides information on the review of site data and the determination of data quality needs for sampling (see the box below).

OVERVIEW OF DQO GUIDANCE

According to the DQO guidance (EPA 1987a and b), DQO are qualitative and quantitative statements established prior to data collection, which specify the quality of the data required to support Agency decisions during remedial response activities. The DQO for a particular site vary according to the end use of the data (i.e., whether the data are collected to support preliminary assessments/site inspections, remedial investigations/feasibility studies, remedial designs, or remedial actions).

The DQO process consists of three stages. In Stage 1 (Identify Decision Types), all available site information is compiled and analyzed in order to develop a conceptual model of the site that describes suspected sources, contaminant pathways, and potential receptors. The outcome of Stage 1 is a definition of the objectives of the site investigation and an identification of data gaps. Stage 2 (Identify Data Uses/Needs) involves specifying the data necessary to meet the objectives set in Stage 1, selecting the sampling approaches and the analytical options for the site, and evaluating multiple-option approaches to allow more timely or cost-effective data collection and evaluation. In Stage 3 (Design Data Collection Program), the methods to be used to obtain data of acceptable quality are specified in such products as the SAP or the workplan.

Use of this guidance will help ensure that all environmental data collected in support of RI/FS activities are of known and documented quality.

4.1.5 OTHER DATA CONCERNS

The simple existence of a data collection plan does not guarantee usable data. The risk assessor should plan an active role in oversight of data collection to ensure that relevant data have been obtained. (See Section 4.9 for more information on the active role that the risk assessor must play.)

After data have been collected, they should be carefully reviewed to identify reliable, accurate, and verifiable numbers that can be used to quantify risks. All analytical data must be evaluated to identify the chemicals of potential concern (i.e., those to be carried through the risk assessment). Chapter 5 discusses the criteria to be considered in selecting the subset of chemical data appropriate for baseline risk assessment. Data that do not meet the criteria are not included in the quantitative risk assessment; they can be discussed qualitatively in the risk assessment report, however, or may be the basis for further investigation.

4.2 REVIEW OF AVAILABLE SITE INFORMATION

Available site information must be reviewed to (1) determine basic site characteristics, (2) initially identify potential exposure pathways and exposure points, and (3) help determine data needs (including modeling needs). All available site information (i.e., information existing at the start of the RI/FS) should be reviewed in accordance with Stage 1 of the DQO process. Sources of available site information include:

- RI/FS scoping information;
- PA/SI data and Hazard Ranking System (HRS) documentation;
- listing site inspection (LSI) data (formally referred to as expanded site inspection, or ESI);
- photographs (e.g., EPA's Environmental Photographic Interpretation Center [EPIC]);
- records on removal actions taken at the site; and
- information on amounts of hazardous substances disposed (e.g., from site records).

If available, LSI (or ESI) data are especially useful because they represent fairly extensive site studies.

Based on a review of the existing data, the risk assessor should formulate a conceptual model of the site that identifies all potential or suspected sources of contamination, types and concentrations of contaminants detected at the site, potentially contaminated media, and potential exposure pathways, including receptors (see Exhibit 4-1). As discussed previously, identification of potential exposure pathways, especially the exposure points, is a key element in the determination of data needs for the risk assessment. Details concerning development of a conceptual model for a site are provided in the DQO guidance (EPA 1987a,b) and the RI/FS guidance (EPA 1988a).

In most cases, site information available at the start of the RI/FS is insufficient to fully characterize the site and the potential exposure pathways. The conceptual model developed at this stage should be adequate to determine the remaining data needs. The remainder of this chapter addresses risk assessment data needs in detail.

4.3 ADDRESSING MODELING PARAMETER NEEDS

As discussed in detail in Chapter 6, contaminant release, transport, and fate models are often needed to supplement monitoring data when estimating exposure concentrations. Therefore, a preliminary site modeling strategy should be developed during RI/FS scoping to allow model input data requirements to be incorporated into the data collection requirements. This preliminary identification of models and other related data requirements will ensure that data for model calibration and validation are collected along with other physical and chemical data at the site. Exhibit 4-2 lists (by medium) several site-specific parameters often needed to incorporate fate and transport models in risk assessments.

Although default values for some modeling parameters are available, it is preferable to obtain site-specific values for as many input parameters as is feasible. If the model is not sensitive to a particular parameter for which a default value is available, then a default value may be used. Similarly, default values may be used if obtaining the site-specific model parameter would be too time consuming or expensive. For example, certain airborne dust emission models use a default value for the average wind speed at the site; this is done because representative measurements of wind speed at the site would involve significant amounts of time (i.e., samples would have to be collected over a large part of the year).

Some model parameters are needed only if the sampling conducted at a site is sufficient to support complex models. Such model parameters may not be necessary if only simple fate and transport models are used in the risk assessment.

4.4 DEFINING BACKGROUND SAMPLING NEEDS

Background sampling is conducted to distinguish site-related contamination from naturally occurring or other non-site-related levels of chemicals. The following subsections define the types of background contamination and provide guidance on the appropriate location and number of background samples.

4.4.1 TYPES OF BACKGROUND

There are two different types of background levels of chemicals:

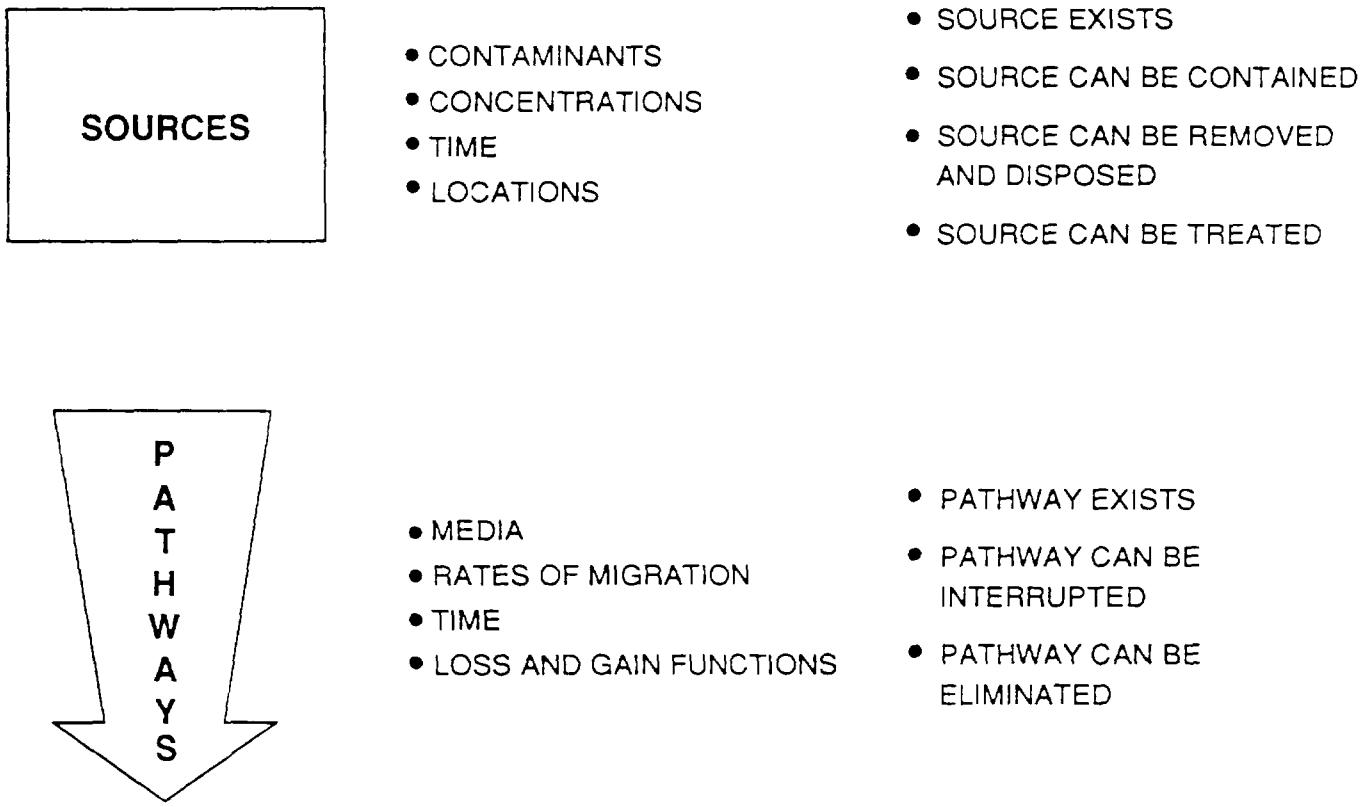
(1) naturally occurring levels, which are ambient concentrations of chemicals present in the environment that have not been influenced by humans (e.g., aluminum, manganese); and

(2) anthropogenic levels, which are concentrations of chemicals that are present in the environment due to human-made, non-site sources (e.g., industry, automobiles).

Background can range from localized to ubiquitous. For example, pesticides -- most of which are not naturally occurring (anthropogenic) -- may be ubiquitous in certain areas (e.g.,

EXHIBIT 4-1

ELEMENTS OF A CONCEPTUAL EVALUATION MODEL



SOURCE: EPA 1987a

EXHIBIT 4-2

EXAMPLES OF MODELING PARAMETERS FOR WHICH INFORMATION MAY NEED TO BE OBTAINED DURING A SITE SAMPLING INVESTIGATION

Type of Modeling	Modeling Parameters[a]
Source Characteristics	Geometry, physical/chemical conditions, emission rate, emission strength, geography
Soil	Particle size, dry weight, pH, redox potential, mineral class, organic carbon and clay content, bulk density, soil porosity
Ground-water	Head measurements, hydraulic conductivity (pump and slug test results), saturated thickness of aquifer, hydraulic gradient, pH, redox potential, soil-water partitioning
Air	Prevailing wind direction, wind speeds, stability class, topography, depth of waste, contaminant concentration in soil and soil gas, fraction organic content of soils, silt content of soils, percent vegetation, bulk density of soil, soil porosity
Surface Water	Hardness, pH, redox potential, dissolved oxygen, salinity, temperature, conductivity, total suspended solids, flow rates and depths for rivers/streams, estuary and embayment parameters such as tidal cycle, saltwater incursion extent, depth and area, lake parameters such as area, volume, depth, depth to thermocline
Sediment	Particle size distribution, organic content, pH, benthic oxygen conditions, water content
Biota	Dry weight, whole body, specific organ, and/or edible portion chemical concentrations, percent moisture, lipid content, size/age, life history stage

[a] These parameters are not necessarily limited to the type of modeling with which they are associated in this exhibit. For example, many of the parameters listed for surface water are also appropriate for sediments.

agricultural areas); salt runoff from roads during periods of snow may contribute high ubiquitous levels of sodium. Polycyclic aromatic hydrocarbons (PAHs) and lead are other examples of anthropogenic, ubiquitous chemicals, although these chemicals also may be present at naturally occurring levels in the environment due to natural sources (e.g., forest fires may be a source of PAHs, and lead is a natural component of soils in some areas).

4.4.2 BACKGROUND SAMPLING LOCATIONS

Background samples are collected at or near the hazardous waste site in areas not influenced by site contamination. They are collected from each medium of concern in these offsite areas. That is, the locations of background samples must be areas that could not have received contamination from the site, but that do have the same basic characteristics as the medium of concern at the site.

Identifying background location requires knowing which direction is upgradient/upwind/upstream. In general, the direction of water flow tends to be relatively constant, whereas the direction of air flow is constantly changing. Therefore, the determination of background locations for air monitoring requires constant and concurrent monitoring of factors such as wind direction.

4.4.3 BACKGROUND SAMPLE SIZE

In appropriate circumstances, statistics may be used to evaluate background sample data. Because the number of background samples collected is important for statistical hypothesis testing, at some sites a statistician should be consulted when determining background sample size. At all sites, the RPM should decide the level of statistical analysis applicable to a particular situation.

Often, rigorous statistical analyses are unnecessary because site- and non-site-related contamination clearly differ. For most sites, the issue will not be whether a difference in chemical concentrations can be demonstrated between contaminated and background areas, but rather that of establishing a reliable representation of the extent (in three dimensions) of a contaminated area. However, statistical analyses are required at some sites, making a basic understanding of statistics necessary. The following discussion outlines some basic statistical concepts in the context of background data evaluation for risk assessment. (A general statistics textbook should be reviewed for additional detail. Also, the box below lists EPA guidance that might be useful.)

STATISTICAL METHODS GUIDANCE

Statistical Methods for Evaluating Groundwater Monitoring Data from Hazardous Waste Facilities (EPA 1988b)

Surface Impoundment Clean Closure Guidance Manual (EPA 1988c)

Love Canal Emergency Declaration Area Habitability Study (EPA 1988d)

Soils Sampling Quality Assurance Guide (EPA 1989b)

A statistical test of a hypothesis is a rule used for deciding whether or not a statement (i.e., the null hypothesis) should be rejected in favor of a specified alternative statement (i.e., the alternative hypothesis). In the context of background contamination at hazardous waste sites, the null hypothesis can be expressed as "there is no difference between contaminant concentrations in background areas and onsite," and the alternative hypothesis can be expressed as "concentrations are higher onsite." This expression of the alternative hypothesis implies a one-tailed test of significance.

The number of background samples collected at a site should be sufficient to accept or reject the null hypothesis with a specified likelihood of error. In statistical hypothesis testing there are two types of error. The null hypothesis may be rejected when it is true (i.e., a Type I error), or not rejected when it is false (i.e., a Type II error). An example of a Type I error at a hazardous waste site would be to conclude that contaminant concentrations in onsite soil are higher than background soil concentrations when in fact they

are not. The corresponding Type II error would be to conclude that onsite contaminant concentrations are not higher than background concentrations when in fact they are. A Type I error could result in unnecessary remediation, while a Type II error could result in a failure to clean up a site when such an action is necessary.

In customary notations, α (alpha) denotes the probability that a Type I error will occur, and β (beta) denotes the probability that a Type II error will occur. Most statistical comparisons refer to α, also known as the level of significance of the test. If $\alpha = 0.05$, there is a 5 percent (i.e., 1 in 20) chance that we will conclude that concentrations of contaminants are higher than background when they actually are not.

Equally critical considerations in determining the number of background samples are β and a concept called "power." The power of a statistical test has the value $1 - \beta$ and is defined as the likelihood that the test procedure detects a false null hypothesis. Power functions for commonly used statistical tests can be found in most general statistical textbooks. Power curves are a function of α (which normally is fixed at 0.05), sample size (i.e., the number of background and/or onsite samples), and the amount of variability in the data. Thus, if a 15 percent likelihood of failing to detect a false null hypothesis is desired (i.e., $\beta = 0.15$), enough background samples must be collected to ensure that the power of the test is at least 0.85.

A small number of background samples increases the likelihood of a Type II error. If an insufficient number of background samples is collected, fairly large differences between site and background concentrations may not be statistically significant, even though concentrations in the many site samples are higher than the few background samples. To guard against this situation, the statistical power associated with the comparison of background samples with site samples should be evaluated.

In general, when trying to detect small differences as statistically significant, the number of background samples should be similar to the number of onsite samples that will be used for the comparison(s) (e.g., the number of samples taken from one well). (Note that this does not mean that the background sample size must equal the total number of onsite samples.) Due to the inherent variability of air concentrations (see Section 4.6), background sample size for air needs to be relatively large.

4.4.4 COMPARING BACKGROUND SAMPLES TO SITE-RELATED CONTAMINATION

The medium sampled influences the kind of statistical comparisons that can be made with background data. For example, air monitoring stations and ground-water wells are normally positioned based on onsite factors and gradient considerations. Because of this purposive placement (see Section 4.6.1), several wells or monitors cannot be assumed to be a random sample from a single population and hence cannot be evaluated collectively (i.e., the sampling results cannot be combined). Therefore, the information from each well or air monitor should be compared individually with background.

Because there typically are many site-related, media-specific sampling location data to compare with background, there usually is a "multiple comparison problem" that must be addressed. In general, the probability of experiencing a Type I error in the entire set of statistical tests increases with the number of comparisons being made. If $\alpha = 0.05$, there is a 1 in 20 chance of a Type I error in any single test. If 20 comparisons are being made, it therefore is likely that at least one Type I error will occur among all 20 tests. *Statistical Analysis of Ground-water Monitoring Data at RCRA Facilities* (EPA 1989c) is useful for designing sampling plans for comparing information from many fixed locations with background.

It may be useful at times to look at comparisons other than onsite versus background. For example, upgradient wells can be compared with downgradient wells. Also, there may be several areas within the site that should be compared for differences in site-related contaminant concentration. These areas of concern should be established before sampling takes place. If a more complicated comparison scheme is planned, a statistician should be consulted frequently to help distribute the sampling effort and design the analysis.

A statistically significant difference between background samples and site-related contamination should not, by itself, trigger a cleanup action. The remainder of this manual still must be applied so that the toxicological -- rather than simply the statistical -- significance of the contamination can be ascertained.

4.5 PRELIMINARY IDENTIFICATION OF POTENTIAL HUMAN EXPOSURE

A preliminary identification of potential human exposure provides much needed information for the SAP. This activity involves the identification of (1) media of concern, (2) areas of concern (i.e., general locations of the media to be sampled),[3] (3) types of chemicals expected at the site, and (4) potential routes of contaminant transport through the environment (e.g., inter-media transfer, food chain). This section provides general information on the preliminary identification of potential human exposure pathways, as well as specific information on the various media. (Also, see Chapter 6 for a detailed discussion of exposure assessment.)

4.5.1 GENERAL INFORMATION

Prior to discussing various specific exposure media, general information on the following is provided: media, types of chemicals, areas of concern, and routes of contaminant transport is addressed.

Media of concern (including biota). For risk assessment purposes, media of concern at a site are:

- any currently contaminated media to which individuals may be exposed or through which chemicals may be transported to potential receptors; and
- any currently uncontaminated media that may become contaminated in the future due to contaminant transport.

Several medium-specific factors in sampling may influence the risk assessment. For example, limitations in sampling the medium may limit the detailed evaluation of exposure pathways described in Chapter 6. To illustrate this, if soil samples are not collected at the surface of a site, then it may not be possible to accurately evaluate potential exposures involving direct contact with soils or exposures involving the release of contaminants from soils via wind erosion (with subsequent inhalation of airborne contaminants by exposed individuals). Therefore, based on the conceptual model of the site discussed previously, the risk assessor should make sure that appropriate samples are collected from each medium of concern.

Areas of concern. Areas of concern refer to the general sampling locations at or near the site. For large sites, areas of concern may be treated in the RI/FS as "operable units," and may include several media. Areas of concern also can be thought of as the locations of potentially exposed populations (e.g., nearest residents) or biota (e.g., wildlife feeding areas).

Areas of concern should be identified based on site-specific characteristics. These areas are chosen purposively by the investigators during the initial scoping meeting. Areas of concern should include areas of the site that:

(1) have different chemical types;

(2) have different anticipated concentrations or hot spots;

(3) are a release source of concern;

(4) differ from each other in terms of the anticipated spatial or temporal variability of contamination;

(5) must be sampled using different equipment; and/or

(6) are more or less costly to sample.

In some instances, the risk assessor may want to estimate concentrations that are representative of the site as a whole, in addition to each area of concern. In these cases, two conditions generally should be met in defining areas of concern: (1) the boundaries of the areas of concern should not overlap and (2) all of the areas of concern

together should account for the entire area of the site.

Depending on the exposure pathways that are being evaluated in the risk assessment, it may not be necessary to determine site-wide representative values. In this case, areas of concern do not have to account for the entire area of the site.

Types of chemicals. The types of chemicals expected at a hazardous waste site may dictate the site areas and media sampled. For example, certain chemicals (e.g., dioxins) that bioconcentrate in aquatic life also are likely to be present in the sediments. If such chemicals are expected at a particular site and humans are expected to ingest aquatic life, sampling of sediments and aquatic life for the chemicals may be particularly important.

Due to differences in the relative toxicities of different species of the same chemical (e.g., Cr^{+3} versus Cr^{+6}), the species should be noted when possible.

Routes of contaminant transport. In addition to medium-specific concerns, there may be several potential current and future routes of contaminant transport within a medium and between media at a site. For instance, discharge of ground water or surface runoff to surface water could occur. Therefore, when possible, samples should be collected based on routes of potential transport. For cases in which contamination has not yet reached points of human exposure but may be transported to those areas in the future, sampling between the contaminant source and the exposure locations should be conducted to help evaluate potential future concentrations to which individuals may be exposed (e.g., through modeling). (See Chapter 6 for additional discussion on contaminant transport.)

4.5.2 SOIL

Soil represents a medium of direct contact exposure and often is the main source of contaminants released into other media. As such, the number, location, and type of samples collected from soils will have a significant effect on the risk assessment. See the box on this page for guidance that provides additional detailed information concerning soil sampling, including information on sampling locations, general soil and vegetation conditions, and sampling equipment, strategies, and techniques. In addition to the general sampling considerations discussed previously, the following specific issues related to soil sampling are discussed below: the heterogeneous nature of soils, designation of hot spots, depth of samples, and fate and transport properties.

SOIL SAMPLING GUIDANCE

Test Methods for Evaluating Solid Waste (SW-846): Physical/Chemical Methods (EPA 1986a)

Field Manual for Grid Sampling of PCB Spill Sites to Verify Cleanups (EPA 1986b)

A Compendium of Superfund Field Operations Methods (EPA 1987c)

Soil Sampling Quality Assurance Guide (EPA Review Draft 1989b)

Heterogeneous nature of soils. One of the largest problems in sampling soil (or other solid materials) is that its generally heterogeneous nature makes collection of representative samples difficult (and compositing of samples virtually impossible -- see Section 4.6.3). Therefore, a large number of soil samples may be required to obtain sufficient data to calculate an exposure concentration. Composite samples sometimes are collected to obtain a more homogeneous sample of a particular area; however, as discussed in a later section, compositing samples also serves to mask contaminant hot spots (as well as areas of low contaminant concentration).

Designation of hot spots. Hot spots (i.e., areas of very high contaminant concentrations) may have a significant impact on direct contact exposures. The sampling plan should consider characterization of hot spots through extensive sampling, field screening, visual observations, or a combination of the above.

Depth of samples. Sample depth should be applicable for the exposure pathways and contaminant transport routes of concern and should be chosen purposively within that depth interval. If a depth interval is chosen purposively, a random procedure to select a sampling point may be established. Assessment of surface exposures will be more certain if samples are collected from the shallowest depth that can be practically obtained, rather than, for example, zero to two feet. Subsurface soil samples are important, however, if soil disturbance is likely or if leaching of chemicals to ground water is of concern, or if the site has current or potential agricultural uses.

Fate and transport properties. The sampling plan should consider physical and chemical characteristics of soil that are important for evaluating fate and transport. For example, soil samples being collected to identify potential sources of ground-water contamination must be able to support models that estimate both quantities of chemicals leaching to ground water and the time needed for chemicals to leach to and within the ground water.

4.5.3 GROUND WATER

Considerable expense and effort normally are required for the installation and development of monitoring wells and the collection of ground-water samples. Wells must not introduce foreign materials and must provide a representative hydraulic connection to the geologic formations of interest. In addition, ground-water samples need to be collected using an approach that adequately defines the contaminant plume with respect to potential exposure points. Existing potential exposure points (e.g., existing drinking water wells) should be sampled.

More detailed information concerning ground-water sampling considerations (e.g., sampling equipment, types, and techniques) can be found in the references in the box on this page. In addition to the general sampling considerations discussed previously in Section 4.5.1, those specific for ground water -- hydrogeologic properties, well location and depth, and filtered vs. unfiltered samples -- are discussed below.

GROUND-WATER SAMPLING GUIDANCE

Practical Guide to Ground-water Sampling (EPA 1985a)

A Compendium of Superfund Field Operations Methods (EPA 1987c)

Handbook: Ground Water (EPA 1987d)

Statistical Methods for Evaluating Ground Water from Hazardous Waste Facilities (EPA 1988b)

Guidance on Remedial Actions for Contaminated Ground Water at Superfund Sites (EPA 1988e)

Ground-water Sampling for Metals Analyses (EPA 1989d)

Hydrogeologic properties. The extent to which the hydrogeologic properties (e.g., hydraulic conductivity, porosity, bulk density, fraction organic carbon, productivity) of the aquifer(s) are characterized may have a significant effect on the risk assessment. The ability to estimate future exposure concentrations depends on the extent to which hydrogeologic properties needed to evaluate contaminant migration are quantified. Repetitive sampling of wells is necessary to obtain samples that are unaffected by drilling and well development and that accurately reflect hydrogeologic properties of the aquifer(s).

Well location and depth. The location of wells should be such that both the horizontal and vertical extent of contamination can be characterized. Separate water-bearing zones may have different aquifer classifications and uses and therefore may need to be evaluated separately in the risk assessment. In addition, sinking or floating layers of contamination may be present at different depths of the wells.

Filtered vs. unfiltered samples. Data from filtered and unfiltered ground-water samples are useful for evaluating chemical migration in ground water, because comparison of chemical

concentrations in unfiltered versus filtered samples can provide important information on the form in which a chemical exists in ground water. For instance, if the concentration of a chemical is much greater in unfiltered samples compared to filtered samples, it is likely that the majority of the chemical is sorbed onto particulate matter and not dissolved in the ground water. This information on the form of chemical (i.e., dissolved or suspended on particulate matter) is important to understanding chemical mobility within the aquifer.

If chemical analysis reveals significantly different concentrations in the filtered and unfiltered samples, try to determine whether there is a high concentration of suspended particles or if apparently high concentrations are due to sampling or well construction artifacts. Supplementary samples can be collected in a manner that will minimize the influence of these artifacts. In addition, consider the effects of the following.

- Filter size. A 0.45 um filter may screen out some potentially mobile particulates to which contaminants are absorbed and thus under-represent contaminant concentrations. (Recent research suggests that a 1.0 um may be a more appropriate filter size.)

- Pumping velocity. Pumping at too high a rate will entrain particulates (to which contaminants are absorbed) that would not normally be mobile; this could overestimate contaminant concentrations.

- Sample oxidation. After contact with air, many metals oxidize and form insoluble compounds that may be filtered out; this may underestimate inorganic chemical concentrations.

- Well construction materials. Corrosion may elevate some metal concentrations even in stainless steel wells.

If unfiltered water is of potable quality, data from unfiltered water samples should be used to estimate exposure (see Chapter 6). The RPM should ultimately decide the type of samples that are collected. If only one type of sample is collected (e.g., unfiltered), justification for not collecting the other type of sample (e.g., filtered) should be provided in the sampling plan.

4.5.4 SURFACE WATER AND SEDIMENT

Samples need to be collected from any nearby surface water body potentially receiving discharge from the site. Samples are needed at a sufficient number of sampling points to characterize exposure pathways, and at potential discharge points to the water body to determine if the site (or some other source) is contributing to surface water/sediment contamination. Some important considerations for surface water/sediment sampling that may affect the risk assessment for various types and portions of water bodies (i.e., lotic waters, lentic waters, estuaries, sediments) are discussed below. More detailed information concerning surface water and sediment sampling, such as selecting sampling locations and sampling equipment, types, and techniques, is provided in the references given in the box below.

SURFACE WATER AND SEDIMENT SAMPLING GUIDANCE

Procedures for Handling and Chemical Analysis of Sediment and Water Samples (EPA and COE 1981)

Sediment Sampling Quality Assurance User's Guide (EPA 1984)

Methods Manual for Bottom Sediment Sample Collection (EPA 1985b)

A Compendium of Superfund Field Operations Methods (EPA 1987c)

An Overview of Sediment Quality in the United States (EPA 1987e)

Proposed Guide for Sediment Collection, Storage, Characterization and Manipulation (The American Society for Testing and Materials, undated)

Lotic waters. Lotic waters are fast-moving waters such as rivers and streams. Variations in mixing across the stream channel and downstream in rivers and streams can make it difficult to obtain representative samples. Although the selection of sampling points will be highly dependent on the exposure pathways of concern for a particular site, samples generally should be taken both toward the middle of the channel where the majority of the flow occurs and along the banks where flow is generally lower. Sampling locations should be downgradient of any possible contaminant sources such as tributaries or effluent outfalls. Any facilities (e.g., dams, wastewater treatment plants) upstream that affect flow volume or water quality should be considered during the timing of sampling. "Background" releases upstream could confound the interpretation of sampling results by diluting contaminants or by increasing contaminant loads. In general, sampling should begin downstream and proceed upstream.

Lentic waters. Lentic waters are slow-moving waters such as lakes, ponds, and impoundments. In general, lentic waters require more samples than lotic waters because of the relatively low degree of mixing of lentic waters. Thermal stratification is a major factor to be considered when sampling lakes. If the water body is stratified, samples from each layer should be obtained. Vertical composites of these layers then may be made, if appropriate. For small shallow ponds, only one or two sample locations (e.g., the intake and the deepest points) may be adequate depending on the exposure pathways of concern for the site. Periodic release of water should be considered when sampling impoundments, as this may affect chemical concentrations and stratification.

Estuaries. Contaminant concentrations in estuaries will depend on tidal flow and salinity-stratification, among other factors. To obtain a representative sample, sampling should be conducted through a tidal cycle by taking three sets of samples on a given day: (1) at low tide; (2) at high tide; and (3) at "half tide." Each layer of salinity should be sampled.

Sediments. Sediment samples should be collected in a manner that minimizes disturbance of the sediments and potential contamination of subsequent samples. Sampling in flowing waters should begin downstream and end upstream. Wading should be avoided. Sediments of different composition (i.e., mud, sand, rock) should not be composited. Again, it is important to obtain data that will support the evaluation of the potential exposure pathways of concern. For example, for pathways such as incidental ingestion, sampling of near-shore sediments may be important; however, for dermal absorption of sediment contaminants during recreational use such as swimming, samples from different points throughout the water body may be important. If ingestion of benthic (bottom-dwelling) species or surface water will be assessed during the risk assessment, sediment should be sampled so that characteristics needed for modeling (e.g., fraction of organic carbon, particle size distribution) can be determined (see Section 4.3).

4.5.5 AIR

Guidance for developing an air sampling plan for Superfund sites is provided in *Procedures for Dispersion Modeling and Air Monitoring for Superfund Air Pathway Analysis* (EPA 1989e). That document is Volume IV of a series of four technical guidance manuals called *Procedures for Conducting Air Pathway Analyses for Superfund Applications* (EPA 1989e-h). The other three volumes of the series include discussions of potential air pathways, air emission sources, and procedures for estimating potential source emission rates associated with both the baseline site evaluation and remedial activities at the site.

Air monitoring information, along with recommendations for proper selection and application of air dispersion models, is included in Volume IV. The section on air monitoring contained in this volume presents step-by-step procedures to develop, conduct, and evaluate the results of air concentration monitoring to characterize downwind exposure conditions from Superfund air emission sources. The first step addressed is the process of collecting and reviewing existing air monitoring information relevant to the specific site, including source, receptor, and environmental data. The second step involves determining the level of sophistication for the air monitoring program; the levels range from simple screening procedures to refined techniques. Selection of a given level will

depend on technical considerations (e.g., detection limits) and available resources. The third step on air monitoring is development of the air monitoring plan and includes determination of the type of air monitors, the number and location of monitors, the frequency and duration of monitoring, sampling and analysis procedures, and QA/QC procedures. Step four details the day-to-day activities related to conducting the air maintenance and calibration, and documentation of laboratory results and QA/QC procedures. The fifth and final step involves the procedures necessary to (1) summarize and evaluate the air monitoring results for validity, (2) summarize the statistics used, (3) determine site-related air concentrations (by comparison of upwind and downwind concentrations), and (4) estimate uncertainties in the results related to the monitoring equipment and program and the analytical techniques used in the laboratory.

Given the difficulties of collecting sufficient air samples to characterize both temporal and spatial variability of air concentrations, modeling -- along or in conjunction with monitoring -- is often used in the risk assessment. For the most efficient sampling program, the section in Volume IV on modeling should be used in conjunction with the section on monitoring.

Volume IV also contains a comprehensive bibliography of other sources of air monitoring and modeling guidance. Note, however, that while this volume contains an extensive discussion on planning and conducting air sampling, it does not provide details concerning particular monitoring equipment and techniques. The box on this page lists some sources of detailed information on air sampling. The following paragraphs address several specific aspects of air sampling: temporal and spatial considerations, emission sources, meteorological conditions.

Temporal and spatial considerations. The goal of air sampling at a site is to adequately characterize air-related contaminant exposures. At a minimum, sampling results should be adequate for predictive short-term and long-term modeling. When evaluating long-term inhalation exposures, sample results should be representative of the long-term average air concentrations at the long-term exposure points. This requires an air sampling plan of sufficient temporal scale to encompass the range of meteorological and climatic conditions potentially affecting emissions, and of sufficient spatial scale to characterize associated air concentrations at potential exposure points. If acute or subchronic exposures resulting from episodes of unusually large emissions are of interest, sampling over a much smaller time scale would be needed.

AIR SAMPLING GUIDANCE

Technical Assistance Document for Sampling and Analysis of Toxic Organic Compounds in Ambient Air (EPA 1983)

A Compendium of Superfund Field Operations Methods (EPA 1987c)

Procedures for Dispersion Modeling and Air Monitoring for Superfund Air Pathway Analysis (EPA 1988f)

Emission sources. Selection of the appropriate type of air monitor will depend on the emission source(s) being investigated as well as the exposure routes to be evaluated. For example, if inhalation of dust is an exposure pathway of concern, then the monitoring equipment must be able to collect respirable dust samples.

Meteorological conditions. Site-specific meteorological conditions should be obtained (e.g., from the National Weather Service) or recorded during the air sampling program with sufficient detail and quality assurance to substantiate and explain the air sampling results. The review of these meteorological data can help indicate the sampling locations and frequencies. Meteorological characteristics also will be necessary if air modeling is to be conducted.

4.5.6 BIOTA

Organisms sampled for human health risk assessment purposes should be those that are likely to be consumed by humans. This may include animals such as commercial and game fish (e.g., salmon, trout, catfish), shellfish (e.g., oysters, clams, crayfish), fowl (e.g., pheasant, duck), and

terrestrial mammals (e.g., rabbit, deer), as well as plants such as grains (e.g., wheat, corn), vegetables (e.g., spinach, carrots), and fruit (e.g., melons, strawberries). An effort should be made to sample species that are consumed most frequently by humans. Guidance for collecting biota samples is provided in the references given in the box below. The following paragraphs address the following special aspects of biota sampling: portion vs. whole sampling, temporal concerns, food preference, fish sampling, involvement by other agencies.

BIOTA SAMPLING GUIDANCE

Food and Drug Administration's *Pesticide Analytical Manual* (FDA 1977)

Cooperative Agreement on the Monitoring of Contaminants in Great Lakes Sport Fish for Human Health Purposes (EPA 1985c)

FDA's *Pesticides and Industrial Chemicals in Domestic Foods* (FDA 1986)

A Compendium of Superfund Field Operations Methods (EPA 1987c)

Guidance Manual for Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish (EPA 1989i)

Portion vs. whole sampling. If only human exposure is of concern, chemical concentrations should be measured only in edible portion(s) of the biota. For many fish species, estimates of concentrations in fillets (skin on or skin off) are the most appropriate measures of exposure concentrations. Whole body measurements may be needed, however, for certain species of fish and/or for environmental risk assessments. For example, for some species, especially small ones (e.g., smelt), whole body concentrations are most appropriate. (See *Risk Assessment Guidance for Superfund: Environmental Evaluation Manual* (EPA 1989a) for more information concerning biota sampling for environmental assessment.) The edible portion of an organism can vary with species and with the potentially exposed subpopulation.

Temporal concerns. Any conditions that may result in non-representative sampling, such as sampling during a species' migration or when plants are not in season, should be avoided.

Food preferences. At some sites, human subpopulations in the area may have different food consumption patterns that need to be evaluated. For example, some people commonly eat the hepatopancreas of shellfish. In these cases, organ concentrations would be most appropriate for estimating exposure. Another example of a less common food preference is consumption of relatively large quantities of seaweed and other less commonly eaten seafoods in some Asian communities.

Fish sampling. It is recommended that fish of "catchable" size be sampled instead of young, small fish because extremely young fish are not likely to be consumed. Older, larger fish also generally are more likely to have been exposed to site-specific contaminants for a long time, although for some species (e.g., salmon) the reverse is true. Both bottom-dwelling (benthic) and open-water species should be sampled if both are used as a food source.

Other agencies. Biota sampling may involve other federal agencies such as the Fish and Wildlife Service or the Department of Agriculture. The equivalent state agencies also may be involved. In such cases, these agencies should be involved early in the scoping process.

4.6 DEVELOPING AN OVERALL STRATEGY FOR SAMPLE COLLECTION

For each medium at a site, there are several strategies for collecting samples. The sampling strategies for a site must be appropriate for use in a quantitative risk assessment; if inappropriate, even the strictest QA/QC procedures associated with the strategy will not ensure the usability of sample results. Generally, persons actually conducting the field investigation will determine the strategy. As discussed in Section 4.1, risk assessors also should be involved in discussions concerning the strategy. The following areas of major concern (from a risk assessment

perspective) are discussed in this section: sample size, sampling location, types of samples, temporal and meteorological factors, field analyses, and cost of sampling. Many of these areas also are discussed for specific media in Section 4.5. See the box in the opposite column and Section 4.5 for more detailed guidance on sampling strategy.

SAMPLING STRATEGY GUIDANCE

Test Methods for Evaluating Solid Waste (SW-846): Physical/Chemical Methods (EPA 1986a)

Data Quality Objectives for Remedial Response Activities: Development Process (EPA 1987a)

Data Quality Objectives for Remedial Response Activities: Example Scenario: RI/FS Activities at a Site with Contaminated Soils and Ground Water (EPA 1987b)

Expanded Site Inspection (ESI) Transitional Guidance for FY 1988 (EPA 1987f)

Quality Assurance Field Operations Manual (EPA 1987g)

Statistical Methods for Evaluating the Attainment of Superfund Cleanup Standards: Volume 1, Soils and Solid Media (EPA 1988f)

Proposed Guidelines for Exposure-related Measurements (EPA 1988g)

Interim Report on Sampling Design Methodology (EPA 1988h)

Standard Handbook of Hazardous Waste Treatment and Disposal (Freeman 1989)

Soil Sampling Quality Assurance Guide (EPA 1989b)

4.6.1 DETERMINE SAMPLE SIZE

Typically, sample size and sample location (see Section 4.6.2) are determined at the same time. Therefore, much of the discussion in this subsection is also pertinent to determining sampling location. The discussion on statistics in Section 4.4 is useful for both sample size and location determinations.

A number of considerations are associated with determining an appropriate number of samples for a risk assessment. These considerations include the following four factors:

(1) number of areas of concern that will be sampled;

(2) statistical methods that are planned;

(3) statistical performance (i.e., variability power, and certainty) of the data that will be collected; and

(4) practical considerations of logistics and cost.

In short, many decisions must be made by the risk assessor related to the appropriate sample size for an investigation. A statistician cannot estimate an appropriate sample size without the supporting information provided by a risk assessor. The following paragraphs discuss these four factors as they relate to sample size determinations.

Areas of concern. A major factor that influences how many samples are appropriate is the number of areas of concern that are established prior to sampling. As discussed in the next subsection, if more areas of concern are identified, then more samples generally will be needed to characterize the site. If the total variability in chemical concentrations is reduced substantially by subdividing the site into areas of concern, then the statistical performance should improve and result in a more accurate assessment of the site.

Statistical methods. A variety of statistical manipulations may need to be performed on the data used in the risk assessment. For example, there may be comparisons with background concentrations, estimates of upper confidence limits on means, and determinations of the probability of identifying hot spots. Each of these analyses requires different calculations for determining a sample size that will yield a

specified statistical performance. Some of the available guidance, such as the Ground-water Monitoring guidance (EPA 1986c), the RCRA Delisting guidance (EPA 1985d), and the Soils Cleanup Attainment guidance (EPA 1988f), address these strategies in detail.

Statistical performance (i.e., variability, power, and certainty). If samples will be taken from an area that is anticipated to have a high degree of variability in chemical concentrations, then many samples may be required to achieve a specified level of certainty and power. If contaminant concentrations in an area are highly variable and only a few samples can be obtained, then the risk assessor should anticipate (1) a great deal of uncertainty in estimating mean concentrations at the site, (2) difficulty in defining the distribution of the data (e.g., normal), and (3) upper confidence limits much higher than the mean. Identification of multiple areas of concern -- each with its own set of samples and descriptive statistics -- will help reduce the total variability if the areas of concern are defined so that they are very different in their contaminant concentration profiles. Risk assessors should discuss in the scoping meeting both the anticipated variability in the data and the desired power and certainty of the statistics that will be estimated from the data.

As discussed in Section 4.4.3, power is the likelihood of detecting a false null hypothesis. Power is particularly important when comparing site characteristics with background. For example, if a 10 percent difference in mean concentrations needs to be determined with 99 percent likelihood (i.e., power of 0.99), a very large number of samples will likely be needed (unless the site and background variabilities are extremely low). On the other hand, if the investigator is only interested in whether the onsite average conditions are 100 times larger than background or can accept a lower chance of detecting the difference if it exists (i.e., a lower power), then a smaller sample size could be accommodated.

The other statistical performance quantity besides power that may need to be specified is the certainty of the calculations. One minus the certainty is the significance level (i.e., α), or false positive rate (see also Section 4.4.3). The higher the desired certainty level (i.e., the lower the significance level), the greater the true difference must be to observe a statistical difference. In the case of upper confidence limits on estimates of mean concentrations, the higher the desired certainty level, the higher will be the upper confidence limit. This follows from the fact that in general, as certainty increases (i.e., α becomes smaller), the size of the confidence interval also increases.

Practical considerations. Finally, questions of practicality, logistics, sampling equipment, laboratory constraints, quality assurance, and cost influence the sample size that will be available for data analysis. After the ideal sample size has been determined using other factors, practical considerations can be introduced to modify the sample size if necessary.

4.6.2 ESTABLISH SAMPLING LOCATIONS

There are three general strategies for establishing sample locations: (1) purposive, (2) completely random, and (3) systematic. Various combinations of these general strategies are possible and acceptable.

Much of the discussion on statistics in the preceding subsection and in Section 4.4 is appropriate here. Typically, a statistician should be consulted when determining sampling location.

Purposive sampling. Although areas of concern are established purposively (e.g., with the intention of identifying contamination), the sampling locations within the areas of concern generally should not be sampled purposively if the data are to be used to provide defensible information for a risk assessment. Purposively identified sampling locations are not discouraged if the objective is site characterization, conducting a chemical inventory, or the evaluation of visually obvious contamination. The sampling results, however, may overestimate or underestimate the true conditions at the site depending on the strategies of the sampling team. Due to the bias associated with the samples, data from purposively identified sampling locations generally should not be averaged, and distributions of these data generally should not be modeled and used to estimate other relevant statistics. After areas of concern have been established purposively, ground-water monitoring well locations, continuous air monitor locations, and soil sample

locations should be determined randomly or systematically within the areas of concern.

Random sampling. Random sampling involves selecting sampling locations in an unbiased manner. Although the investigator may have chosen the area of concern purposively, the location of random sampling points within the area should be independent of the investigator (i.e., unbiased). In addition, the sampling points should be independent of each other; that is, it should not be possible to predict the location of one sampling point based on the location of others. Random sampling points can be established by choosing a series of pairs of random numbers that can be mapped onto a coordinate system that has been established for each area of concern.

Several positive features are associated with data collected in a random sampling program. First, the data can be averaged and used to estimate average concentrations for the area of concern (rather than simply an average of the samples that were acquired). Second, estimates of the uncertainty of the average and the distributional form of the concentration measurements are informative and simple to estimate when they are determined from data that were obtained randomly. Finally, if there is a trend or systematic behavior to the chemical concentrations (e.g., sampling is occurring along a chemical gradient), then random sampling is preferred because it reduces the likelihood that all of the high concentration locations are sampled to the exclusion of the low concentration locations.

Systematic sampling. Systematic sample locations are established across an area of concern by laying out a grid of sampling locations that follow a regular pattern. Systematic sampling ensures that the sampling effort across the area of concern is uniform and that samples are collected in each area. The sampling location grid should be determined by randomly identifying a single initial location from which the grid is constructed. If such a random component is not introduced, the sample is essentially purposive. The grid can be formed in several patterns including square, rectangular, triangular, or hexagonal, depending on the shape of the area. A square pattern is often the simplest to establish. Systematic sampling is preferable to other types of sampling if the objective is to search for small areas with elevated concentrations. Also, geostatistical characterizations -- as described in the DQO guidance (EPA 1987a,b) -- are best done with data collected from a systematic sample.

Disadvantages of systematic sampling include the need for special variance calculations in order to estimate confidence limits on the average concentration. The Soils Cleanup Attainment guidance (EPA 1988f) discusses these calculations in further detail.

4.6.3 DETERMINE TYPES OF SAMPLES

Another item of concern is the determination of the types of samples to be collected. Basically, two types of samples may be collected at a site: grab and composite.

Grab samples. Grab samples represent a single unique part of a medium collected at a specific location and time.

Composite samples. Composite samples -- sometimes referred to as continuous samples for air -- combine subsamples from different locations and/or times. As such, composite samples may dilute or otherwise misrepresent concentrations at specific points and, therefore, should be avoided as the only inputs to a risk assessment. For media such as soil, sediment, and ground water, composite samples generally may be used to assess the presence or absence of contamination; however, they may be used in risk assessment only to represent average concentrations (and thus exposures) at a site. For example, "hot spots" cannot be determined using composite samples. For surface water and air, composite samples may be useful if concentrations and exposures are expected to vary over time or space, as will often be the case in a large stream or river. Composites then can be used to estimate daily or monthly average concentrations, or to account for stratification due to depth or varying flow rates across a stream.

4.6.4 CONSIDER TEMPORAL AND METEOROLOGICAL FACTORS

Temporal (time) and meteorological (weather) factors also must be considered when determining sampling strategies. The sampling

design should account for fluctuations in chemical concentrations due to these factors because in general, the variability in sampling results increases with increasing complexity of these factors. When these factors are complex, specialized and detailed sampling designs are needed to maintain a constant and certain level of accuracy in the results. Countering this need, however, is the cost of the sampling. The following paragraphs address the interactions of the single sampling event, annual/seasonal sampling cycle, variability estimation, and the cost of sampling.

Single sampling event. Variability measures from a single sampling event will underestimate the overall variability of concentrations across an area of concern, which in turn will result in the underestimation of the confidence limits on the mean. The reason for this underestimation is that temporal variability is not included in an evaluation of the total environmental variability at the site.

Annual/seasonal sampling cycle. The ideal sampling strategy incorporates a full annual sampling cycle. If this strategy cannot be accommodated in the investigation, at least two sampling events should be considered. These sampling events should take place during opposite seasonal extremes. For example, sampling periods that may be considered extremes in temporal sampling include (1) high water/low water, (2) high recharge/low recharge, (3) windy/calm, and (4) high suspended solids/clear water. This type of sampling requires some prior knowledge of regional seasonal dynamics. In addition, a sampling team that can mobilize rapidly might be needed if the particular year of sampling is not typical and the extreme conditions occur at an unusual time. See the box on this page for examples of seasonal variability.

Variability estimation. The simple variance estimators that are often used in risk assessment require that the data are independent or uncorrelated. Certain types of repeated samples, however, (e.g., those from ground-water wells or air monitors) actually are time series data that might be correlated. In other words, the concentration of a contaminant in an aquifer measured at a well on a given day will depend, in part, on what the concentration in the aquifer was on the previous day. To reduce this dependence (e.g., due to seasonal variability), sampling of ground-water wells and air monitors should be either separated in time or the data should be evaluated using statistical models with variance estimators that can accommodate a correlation structure. Otherwise, if time series data that are correlated are treated as a random sample and used to calculate upper confidence limits on the mean, the confidence limits will be underestimated.

SEASONAL VARIABILITY

Regardless of the medium sampled, sample composition may vary depending on the time of year and weather conditions when the sample is collected. For example, rain storms may greatly alter soil composition and thus affect the types and concentrations of chemicals present on solid material; heavy precipitation and runoff from snowmelt may directly dilute chemical concentrations or change the types of chemicals present in surface water; heavy rain also may result in sediment loading to water bodies, which could increase contamination or affect the concentrations of other contaminants through adsorption and settling in the water column; if ground-water samples are collected from an area heavily dependent on ground water for irrigation, the composition of a sample collected during the summer growing season may greatly differ from the composition of a sample collected in the winter.

Ideally, samples of various media should be collected in a manner that accounts for time and weather factors. If seasonal fluctuations cannot be characterized in the investigations, details concerning meteorological, seasonal, and climatic conditions during sampling must be documented.

4.6.5 USE FIELD SCREENING ANALYSES

An important component of the overall sampling strategy is the use of field screening analyses. These types of analyses utilize instruments that range from relatively simple (e.g., hand-held organic vapor detectors) to more sophisticated (e.g., field gas chromatographs). (See *Field Screening Methods Catalog* [EPA 1987h] for more information.) Typically, field screening is used to provide threshold indications of contamination. For example, on the basis of soil gas screening, the field investigation team may determine that contamination of a particular area

is indicated and therefore detailed sampling is warranted. Although field screening results usually are not directly used in the risk assessment, they are useful for streamlining sampling and the overall RI/FS process.

4.6.6 CONSIDER TIME AND COST OF SAMPLING

Two primary constraints in sampling are time and cost. Time consuming or expensive sampling strategies for some media may prohibit multiple sampling points. For example, multiple ground-water wells and air monitors on a grid sampling pattern are seldom located within a single area of concern. However, multiple surface water and soil samples within each area of concern are easier to obtain. In the case of ground water and air, several areas of concern may have to be collapsed into a single area so that multiple samples will be available for estimating environmental variability or so that the dynamics of these media can be evaluated using accepted models of fate and transport.

In general, it is important to remember when developing the sampling strategy that detailed sampling must be balanced against the time and cost involved. The goal of RI/FS sampling is not exhaustive site characterization, but rather to provide sufficient information to form the basis for site remediation.

4.7 QA/QC MEASURES

This section presents an overview of the following quality assurance/quality control (QA/QC) considerations that are of particular importance for risk assessment sampling: sampling protocol, sampling devices, QC samples, collection procedures, and sample preservation. Note, however, that the purpose of this discussion is to provide background information; the risk assessor will not be responsible for most QA/QC evaluations.

The *Quality Assurance Field Operations Manual* (EPA 1987g) should be reviewed. In addition, the EPA Environmental Monitoring Support Laboratory in Las Vegas, Nevada, (EMSL-LV) currently is writing a guidance document concerning the development of quality assurance sample designs for Superfund site investigations. Regional QA/QC contacts (e.g., the regional Environmental Services Division) or EMSL-LV should be consulted if more information concerning QA/QC procedures for sampling is desired.

4.7.1 SAMPLING PROTOCOL

The sampling protocol for a risk assessment should include the following:

- objectives of the study;
- procedures for sample collection, preservation, handling and transport; and
- analytical strategies that will be used.

Presenting the objectives of the RI sampling is particularly important because these objectives also will determine the focus of the risk assessment. There should be instructions on documenting conditions present during sampling (e.g., weather conditions, media conditions). Persons collecting samples must be adequately trained and experienced in sample collection. Test evaluations of the precision attained by persons involved in sample collection should be documented (i.e., the individual collecting a sample should do so in a manner that ensures that a homogeneous, valid sample is reproducibly obtained). The discussion of analytical strategies should specify quantitation limits to be achieved during analyses of each medium.

4.7.2 SAMPLING DEVICES

The devices used to collect, store, preserve, and transport samples must not alter the sample in any way (i.e., the sampling materials cannot be reactive, sorptive, able to leach analytes, or cause interferences with the laboratory analysis). For example, if the wrong materials are used to construct wells for the collection of ground-water samples, organic chemicals may be adsorbed to the well materials and not be present in the collected sample.

4.7.3 QC SAMPLES

Field QC samples (e.g., field blanks, trip blanks, duplicates, split samples) must be collected, stored, transported, and analyzed in a manner identical to those for site samples. The meaning and purpose of blank samples are discussed in detail in Chapter 5. Field duplicate samples are usually two samples collected simultaneously from the same sampling location and are used as measures of either the homogeneity of the medium sampled in a particular location or the precision in sampling. Split samples are usually one sample that is divided into equal fractions and sent to separate independent laboratories for analysis. These split samples are used to check precision and accuracy of laboratory analyses. Samples may also be split in the same laboratory, which can provide information on precision. The laboratory analyzing the samples should not be aware of the identity of the field QC samples (e.g., labels on QC samples should be identical to those on the site samples).

4.7.4 COLLECTION PROCEDURES

Collection procedures should not alter the medium sampled. The general environment surrounding the location of the sample should remain the same so that the collected samples are representative of the situation due to the site conditions, not due to conditions posed by the sampling equipment.

4.7.5 SAMPLE PRESERVATION

Until analysis by the laboratory, any chemicals in the samples must be maintained at close to the same concentrations and identities as in the environment from which they came. Therefore, special procedures may be needed to preserve the samples during the period between collection and analysis.

4.8 SPECIAL ANALYTICAL SERVICES

EPA's SAS, operated by the CLP, may be necessary for two main reasons: (1) the standard laboratory methods used by EPA's Routine Analytical Services (RAS) may not be appropriate (e.g., lower detection limits may be needed),[4] and (2) chemicals other than those on the target compound list (TCL; i.e., chemicals usually analyzed under the Superfund program) may be suspected at the site and therefore may need to be analyzed. A discussion on the RAS detection limits is provided in Chapter 5. Additional information on SAS can be found in the *User's Guide to the Contract Laboratory Program* (EPA 1988i).

In reviewing the historical data at a site, the risk assessor should determine if non-TCL chemicals are expected. As indicated above, non-TCL chemicals may require special sample collection and analytical procedures using SAS. Any such needs should be discussed at the scoping meeting. SAS is addressed in greater detail in Chapter 5.

4.9 TAKING AN ACTIVE ROLE DURING WORKPLAN DEVELOPMENT AND DATA COLLECTION

The risk assessor should be sure to take an active role during workplan development and data collection. This role involves three main steps:

(1) present risk assessment sampling needs at the scoping meeting;

(2) contribute to the workplan and review the Sampling and Analysis Plan; and

(3) conduct interim reviews of outputs of the field investigation.

See Chapter 9 for information on the role of the RPM during workplan development and data collection.

4.9.1 PRESENT RISK ASSESSMENT SAMPLING NEEDS AT SCOPING MEETING

At the scoping meeting, the uses of samples and data to be collected are identified, strategies for sampling and analysis are developed, DQOs are established, and priorities for sample collection

are assigned based on the importance of the data in meeting RI/FS objectives. One of the RI/FS objectives, of course, is the baseline risk assessment. Therefore, the risk assessment data needs and their fit with those of other RI/FS components are discussed. If certain risk assessment sampling needs are judged infeasible by the scoping meeting attendees, all persons involved with site investigation should be made aware of the potential effects of exclusion on the risk assessment.

4.9.2 CONTRIBUTE TO WORKPLAN AND REVIEW SAMPLING AND ANALYSIS PLAN

The outcome of the scoping meeting is the development of a workplan and a SAP. The workplan documents the decisions and evaluations made during the scoping process and presents anticipated future tasks, while the SAP specifies the sampling strategies, the numbers, types, and locations of samples, and the level of quality control. The SAP consists of a quality assurance project plan (QAPjP) and a field sampling plan (FSP). Elements of the workplan and the SAP are discussed in detail in Appendix B of the RI/FS guidance (EPA 1988a). Both the workplan and the SAP generally are written by the personnel who will be involved in the collection of the samples; however, these documents should be reviewed by all personnel who will be using the resulting sample data.

Review the workplan. The workplan should describe the tasks involved in conducting the risk assessment. It also should describe the development of a preliminary assessment of public health and environmental impacts at the site. The risk assessor should review the completed workplan to ensure that all feasible risk assessment sampling needs have been addressed as discussed in the scoping meeting. In particular, this review should focus on the descriptions of tasks related to:

- field investigation (e.g., source testing, media sampling), especially with respect to
  - -- background concentrations by medium,
  - -- quantification of present and future exposures, e.g.,
    - exposure pathways
    - present and potential future land use
    - media that are or may be contaminated
    - locations of actual and potential exposure
    - present concentrations at appropriate exposure points,
  - -- data needs for statistical analysis of the above, and
  - -- data needs for fate and transport models;
- sample analysis/validation, especially with respect to
  - -- chemicals of concern, and
  - -- analytical quantification levels;
- data evaluation; and
- assessment of risks.

In reviewing the above, the precise information necessary to satisfy the remainder of this guidance should be anticipated.

Review the SAP. The risk assessor should carefully review and evaluate all sections of the SAP to determine if data gaps identified in the workplan will be addressed adequately by the sampling program. Of particular importance is the presentation of the objectives. In the QAPjP component of the SAP, the risk assessor should pay particular attention to the QA/QC procedures associated with sampling (e.g., number of field blanks, number of duplicate samples -- see Section 4.8). The SAP should document the detailed, site-specific procedures that will be followed to ensure the quality of the resulting samples. Special considerations in reviewing the SAP are discussed in Section 4.1.3.

In reviewing the FSP, pay particular attention to the information on sample location and frequency, sampling equipment and procedures, and sample handling and analysis. As discussed in Section 4.5, the sampling procedures should address:

- each medium of concern;
- background concentrations;
- all potential exposure points within each medium;
- migration to potential exposure points, including data for models;
- potential exposures based on possible future land uses;
- sufficient data to satisfy concerns about distributions of sampling data and statistics; and
- number and location of samples.

The analytical plans in the FSP should be reviewed to ensure that DQOs set during the scoping meeting will be met.

The SAP may be revised or amended several times during the site investigation. Therefore, a review of all proposed changes to the SAP that potentially may affect the data needs for risk assessment is necessary. Prior to any changes in the SAP during actual sampling, compliance of the changes with the objectives of the SAP must be checked. (If risk assessment objectives are not specified in the original SAP, they will not be considered when changes to an SAP are proposed.)

4.9.3 CONDUCT INTERIM REVIEWS OF FIELD INVESTIGATION OUTPUTS

All sampling results should be reviewed as soon as they are available to determine if the risk assessmen: data needs outlined in the workplan have been met by the sampling. Compare the actual number, types, and locations of samples collected with those planned in the SAP. Sampling locations frequently are changed in the field when access to a planned sampling location is obstructed. The number of samples collected may be altered if, for instance, there is an insufficient amount of a certain medium to collect the planned number of samples (e.g., if several wells are found to be dry).

If certain sampling needs have not been met, then the field investigators should be contacted to determine why these samples were not collected. If possible, the risk assessor should obtain samples to fill these data gaps. If time is critical, Special Analytical Services (see Section 4.7) may be used to shorten the analytical time. If this is not possible, then the risk assessor should evaluate all sampling results as discussed in Chapter 5, documenting the potential effect that these data gaps will have on the quantitative risk assessment. In general, the risk assessment should not be postponed due to these data gaps.

ENDNOTES FOR CHAPTER 4

1. Some information that is appropriate for the assessment of human health risks also may be suitable and necessary for an environmental evaluation of the site. Procedures for conducting an environmental evaluation of the hazardous waste site are outlined in the companion volume of this guidance, the Environmental Evaluation Manual (EPA 1989a), and are not discussed in this chapter.

2. The term "media" refers to both environmental media (e.g., soil) and biota (e.g., fish).

3. "Areas of Concern" within the context of this guidance should be differentiated from the same terminology used by the Great Lakes environmental community. This latter use is defined by the International Joint Commission as an area found to be exceeding the Great Lakes Water Quality Agreement objectives.

4. New routine services that provide lower detection limits are currently under development. Contact the headquarters Analytical Operations Branch for further information.

REFERENCES FOR CHAPTER 4

American Society of Testing and Materials (ASTM). Undated. A Proposed Guide for Sediment Collection, Storage, Characterization, and Manipulation. Draft. Available from G. Allen Burton, Dept of Biological Sciences, Wright State University, Dayton, Ohio 45435.

- Provides information concerning how to collect contaminated sediments, sediment spiking, dilution procedures, and QA/QC. Will probably be in the annual ASTM manual.

Environmental Protection Agency (EPA). 1981. Procedures for Handling and Chemical Analysis of Sediment and Water Samples. Great Lakes Laboratory.

Environmental Protection Agency (EPA). 1983. Technical Assistance Document for Sampling and Analysis of Toxic Organic Compounds in Ambient Air. Office of Research and Development.

- Provides guidance to persons involved in designing and implementing ambient air monitoring programs for toxic organic compounds. Includes guidance on selecting sampling/analytical methods, sampling strategy, QA procedures, and data format. Outlines policy issues.

Environmental Protection Agency (EPA). 1984. Sediment Sampling Quality Assurance User's Guide. Environmental Monitoring Support Laboratory. Las Vegas, NV. NTIS: PB-85-233-542.

- Overview of selected sediment models presented as a foundation for stratification of study of regions and selection of locations for sampling sites, methods of sampling, sampling preparation and analysis. Discussion of rivers, lakes, and estuaries.

Environmental Protection Agency (EPA). 1985a. Practical Guide to Ground-water Sampling. Environmental Research Laboratory. Ada, OK. EPA 600/2-85/104.

- Contains information on laboratory and field testing of sampling materials and procedures. Emphasizes minimizing errors in sampling and analysis.

Environmental Protection Agency (EPA). 1985b. Methods Manual for Bottom Sediment Sample Collection. Great Lakes National Program Office. EPA 905/4-85/004.

- Provides guidance on survey planning, sample collection, document preparation, and quality assurance for sediment sampling surveys. Sample site selection, equipment/containers, collection field observation, preservation, handling custody procedures.

Environmental Protection Agency (EPA). 1985c. Cooperative Agreement on the Monitoring of Contaminants in Great Lakes Sport Fish for Human Health Purposes. Region V, Chicago, IL.

- Discusses sampling protocols and sample composition used for sport fish (chinook salmon, coho salmon, lake trout, and rainbow trout), maximum composite samples (5 fish) and length ranges which would be applicable to hazardous waste sites contaminating lakes or streams used for recreational fishing.

Environmental Protection Agency (EPA). 1985d. Petitions to Delist Hazardous Wastes Guidance Manual. Office of Solid Waste. EPA/530/SW-85/003.

Environmental Protection Agency (EPA). 1986a. Test Methods for Evaluating Solid Waste (SW-846): Physical/Chemical Methods. Office of Solid Waste.

- Provides analytical procedures to test solid waste to determine if it is a hazardous waste as defined under RCRA. Contains information for collecting solid waste samples and for determining reactivity, corrosivity, ignitability, composition of waste, and mobility of waste compounds.

Environmental Protection Agency (EPA). 1986b. Field Manual for Grid Sampling of PCB Spill Sites to Verify Cleanups. Office of Toxic Substances. EPA/560/5-86/017.

- Provides detailed, step-by-step guidance for using hexagonal grid sampling; includes sampling design, collection, QA/QC and reporting.

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- Contains a detailed presentation of the elements and procedures essential to the design and operation of ground-water monitoring systems that meet the goals of RCRA and its regulations. Includes appendices on statistical analysis and some geophysical techniques.

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- Identifies (1) the framework and process by which data quality objectives (DQOs; qualitative and quantitative statements that specify the quality of the data required to support Agency decisions during remedial response activities) are developed and (2) the individuals responsible for development of DQOs. Provides procedures for determining a quantifiable degree of certainty that can be used in making site-specific decisions. Provides a formal approach to integration of DQO development with sampling and analysis plan development. Attempts to improve the overall quality and cost effectiveness of data collection and analysis activities.

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- Resource document that brings together the available technical information in a form convenient for personnel involved in ground-water management. Also addresses minimization of uncertainties in order to make reliable predictions about contamination response to corrective or preventative measures.

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- Provides reader with a consolidated ready reference of general methodologies and activities for conducting inspection work on sites being investigated for the NPL.

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- Provides guidance for the selection and definition of field methods, sampling procedures, and custody responsibilities.

Environmental Protection Agency (EPA). 1987h. Field Screening Methods Catalog. Office of Emergency and Remedial Response.

- Provides a listing of methods to be used during field screening, and includes method descriptions, their application to particular sites, their limitations and uses, instrumentation requirements, detection limits, and precision and accuracy information.

Environmental Protection Agency (EPA). 1988a. Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA. Interim Final. Office of Emergency and Remedial Response. (OSWER Directive 9355.3-01).

- Provides the user (e.g., EPA personnel, state agencies, potentially responsible parties (PRPs), federal facility coordinators, and contractors assisting in RI/FS-related activities) with an overall understanding of the RI/FS process. Includes general information concerning scoping meetings, the development of conceptual models at the beginning of a site investigation, sampling, and analysis.

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- Specifies five different statistical methods that are appropriate for ground-water monitoring. Outlines sampling procedures and performance standards that are designed to help minimize the occurrence of Type I and Type II errors.

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- Provides a formal comparison of samples with background as well as detailed discussions concerning problems associated with sampling to evaluate data.

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- This volume discusses procedures for dispersion modeling and air monitoring for superfund air pathway analyses. Contains recommendations for proper selection and application of air dispersion models and procedures to develop, conduct, and evaluate the results of air concentration monitoring to characterize downwind exposure conditions from Superfund air emission sources.

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- Provides recommended procedures for the conduct of air pathway analyses (APAs) that meet the needs of the Superfund program. The procedures are intended for use by EPA remedial project managers, enforcement project managers, and air experts as well as by EPA Superfund contractors. The emphasis of this volume is to provide a recommended APA procedure relative to the remedial phase of the Superfund process.

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- This volume provides information concerning procedures for developing baseline emissions from landfills and lagoons. Describes baseline emissions from both undisturbed sites and sites where media-disturbing activities are taking place. The procedures described for landfills may be applied to solid hazardous waste, and those for lagoons may be applied to liquid hazardous waste.

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- This volume provides technical guidance for estimating air emissions from remedial activities at NPL sites that may impact local air quality for both onsite workers at a site and the surrounding community while the remedial activities are occurring. Discusses methods to characterize air quality impacts during soil removal, incineration, and air stripping.

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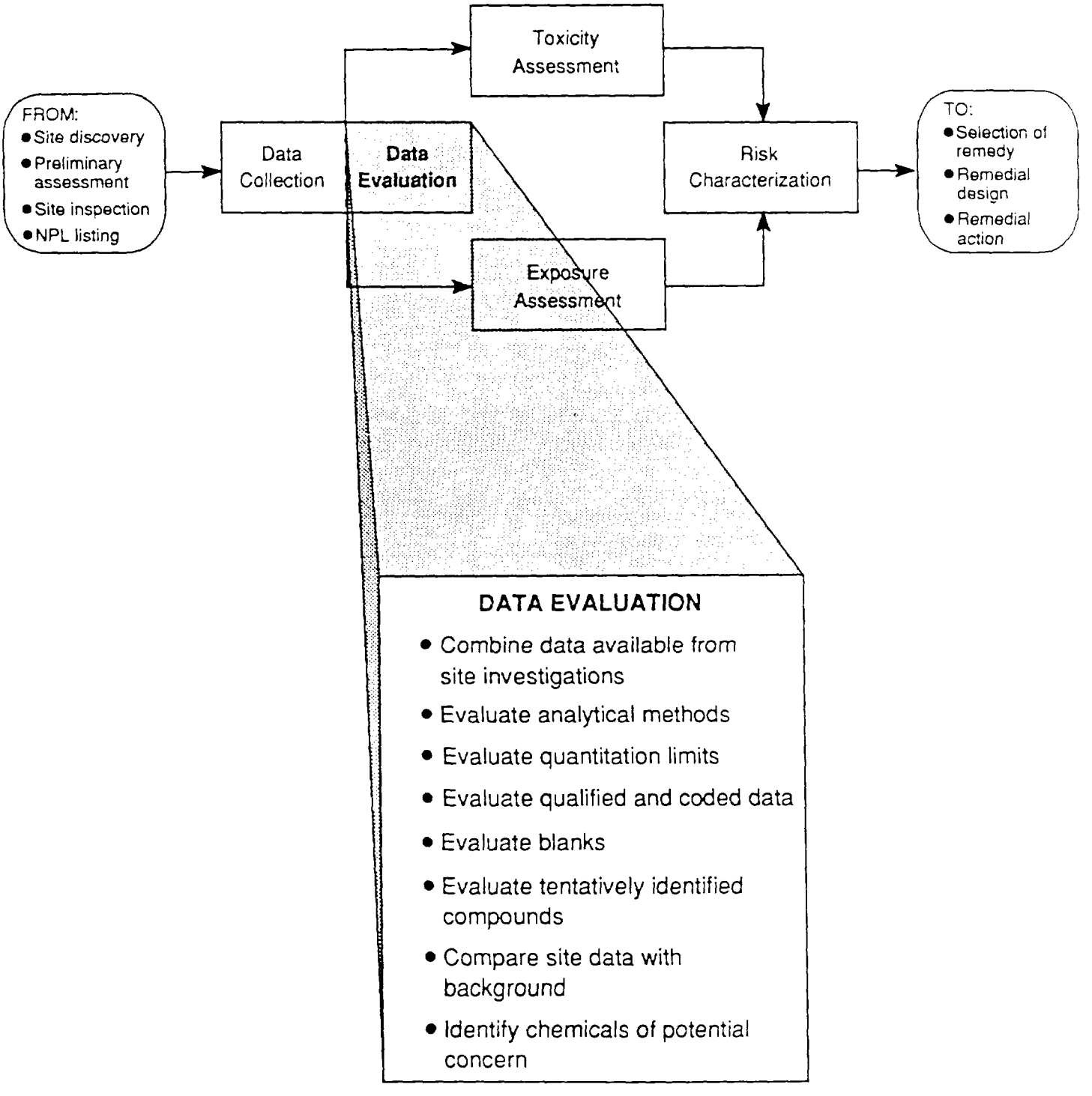
- Provides statistical analysis information by providing sampling plans, statistical tests, parameter estimation procedure techniques, and references to pertinent publications. The statistical techniques discussed are relatively simple, and examples, exercise, and case studies are provided to illustrate procedures.

CHAPTER 5

DATA EVALUATION



CHAPTER 5

DATA EVALUATION

After a site sampling investigation has been completed (see Chapter 4), a large quantity of analytical data is usually available. Each sample may have been analyzed for the presence of over one hundred chemicals, and many of those chemicals may have been detected. The following nine steps should be followed to organize the data into a form appropriate for a baseline risk assessment:

(1) gather all data available from the site investigation and sort by medium (Section 5.1);

(2) evaluate the analytical methods used (Section 5.2);

(3) evaluate the quality of data with respect to sample quantitation limits (Section 5.3);

(4) evaluate the quality of data with respect to qualifiers and codes (Section 5.4);

(5) evaluate the quality of data with respect to blanks (Section 5.5);

(6) evaluate tentatively identified compounds (Section 5.6);

(7) compare potential site-related contamination with background (Section 5.7);

(8) develop a set of data for use in the risk assessment (Section 5.8); and

(9) if appropriate, further limit the number of chemicals to be carried through the risk assessment (Section 5.9).

Prior to conducting any of these steps, the EPA remedial project manager (RPM) should be consulted to determine if certain steps should be modified, added, or deleted as a result of site-specific conditions. Also, some of the steps may be conducted outside the context of the risk assessment (e.g., for the feasibility study). The rationale for not evaluating certain data based on any of these steps must be fully discussed in the text of the risk assessment report.

The following sections address each of the data evaluation steps in detail, and Exhibit 5-1 presents a flowchart of the process. The outcome of this evaluation is (1) the identification of a set

ACRONYMS FOR CHAPTER 5

CLP = Contract Laboratory Program
CRDL = Contract-Required Detection Limit
CRQL = Contract-Required Quantitation Limit
DL = Detection Limit
FIT = Field Investigation Team
IDL = Instrument Detection Limit
MDL = Method Detection Limit
ND = Non-detect
PE = Performance Evaluation
PQL = Practical Quantitation Limit
QA/QC = Quality Assurance/Quality Control
QL = Quantitation Limit
RAS = Routine Analytical Services
SAS = Special Analytical Services
SMO = Sample Management Office
SOW = Statement of Work
SQL = Sample Quantitation Limit
SVOC = Semivolatile Organic Chemical
TCL = Target Compound List
TIC = Tentatively Identified Compound
TOC = Total Organic Carbon
TOX = Total Organic Halogens
VOC = Volatile Organic Chemical

DEFINITIONS FOR CHAPTER 5

Chemicals of Potential Concern. Chemicals that are potentially site-related and whose data are of sufficient quality for use in the quantitative risk assessment.

Common Laboratory Contaminants. Certain organic chemicals (considered by EPA to be acetone, 2-butanone, methylene chloride, toluene, and the phthalate esters) that are commonly used in the laboratory and thus may be introduced into a sample from laboratory cross-contamination, not from the site.

Contract-required Quantitation Limit (CRQL). Chemical-specific levels that a CLP laboratory must be able to routinely and reliably detect and quantitate in specified sample matrices. May or may not be equal to the reported quantitation limit of a given chemical in a given sample.

Detection Limit (DL). The lowest amount that can be distinguished from the normal "noise" of an analytical instrument or method.

Non-detects (NDs). Chemicals that are not detected in a particular sample above a certain limit, usually the quantitation limit for the chemical in that sample. Non-detects may be indicated by a "U" data qualifier.

Positive Data. Analytical results for which measurable concentrations (i.e., above a quantitation limit) are reported. May have data qualifiers attached (except a U, which indicates a non-detect).

Quantitation Limit (QL). The lowest level at which a chemical can be accurately and reproducibly quantitated. Usually equal to the instrument detection limit multiplied by a factor of three to five, but varies for different chemicals and different samples.

of chemicals that are likely to be site-related and (2) reported concentrations that are of acceptable quality for use in the quantitative risk assessment. If the nine data evaluation steps are followed, the number of chemicals to be considered in the remainder of the risk assessment usually will be less than the number of chemicals initially identified. Chemicals remaining in the quantitative risk assessment based upon this evaluation are referred to in this guidance as "chemicals of potential concern."

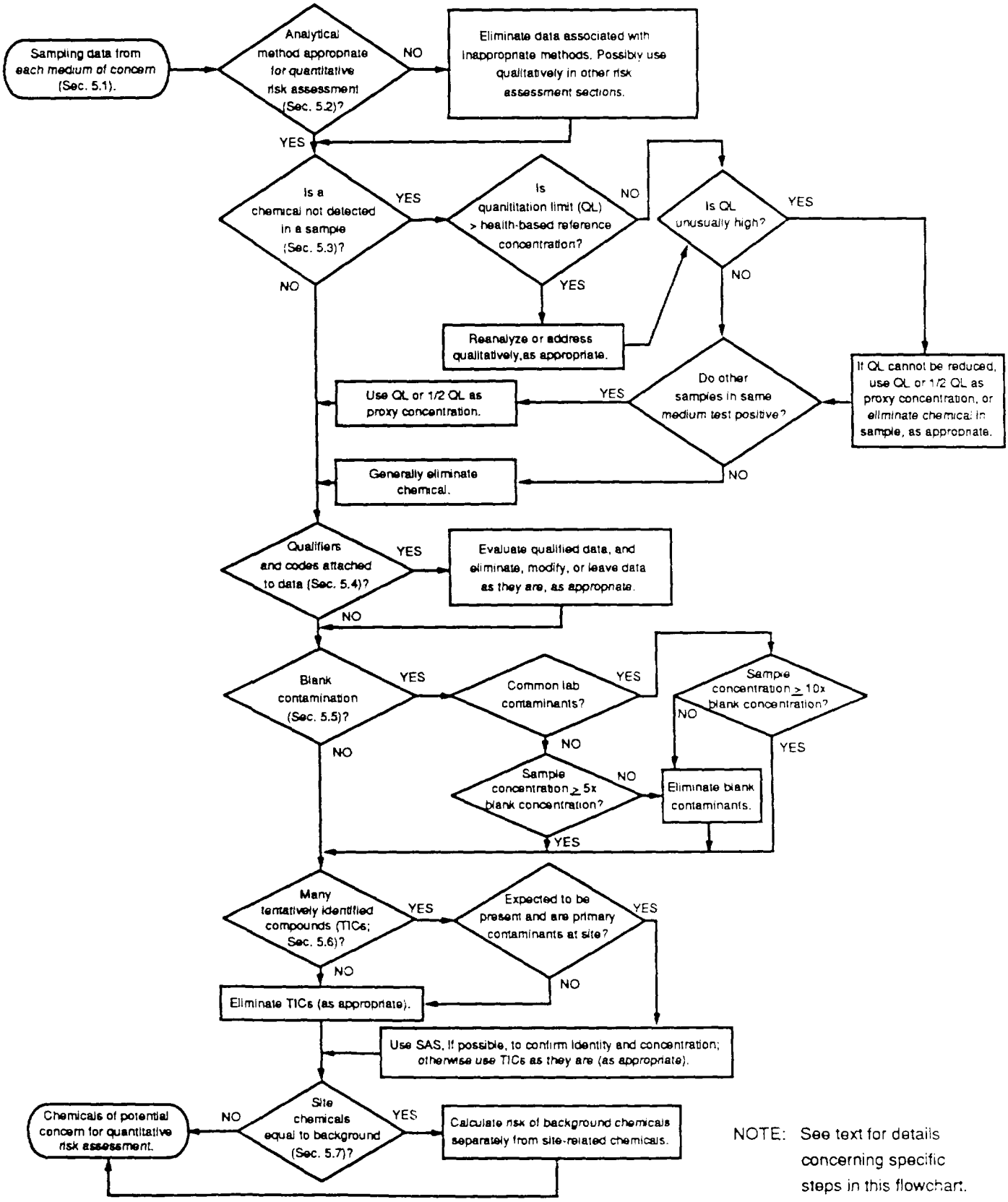
5.1 COMBINING DATA AVAILABLE FROM SITE INVESTIGATIONS

Gather data, which may be from several different sampling periods and based on several different analytical methods, from all available sources, including field investigation team (FIT) reports, remedial investigations, preliminary site assessments, and ongoing site characterization and alternatives screening activities. Sort data by medium. A useful table format for presenting data is shown in Exhibit 5-2.

Evaluate data from different time periods to determine if concentrations are similar or if changes have occurred between sampling periods. If the methods used to analyze samples from different time periods are similar in terms of the types of analyses conducted and the QA/QC procedures followed, and if the concentrations between sampling periods are similar, then the data may be combined for the purposes of quantitative risk assessment in order to obtain more information to characterize the site. If concentrations of chemicals change significantly between sampling periods, it may be useful to keep the data separate and evaluate risks separately. Alternatively, one could use only the most recent data in the quantitative risk assessment and evaluate older data in a qualitative analysis of changes in concentrations over time. The RPM should be consulted on the elimination of any data sets from the risk assessment, and justification for such elimination must be fully described in the risk assessment report.

EXHIBIT 5-1

DATA EVALUATION



NOTE: See text for details concerning specific steps in this flowchart.

EXHIBIT 5-2

EXAMPLE OF OUTPUT FORMAT FOR VALIDATED DATA

	Area X		
Sample Medium	Soil	Soil	Soil
Sample ID	SRB-3-1	SRB-3-1DU	SRB-3-2
Sample or Screen Depth	0-1'	0-1'	2-4'
Date Collected	12/14/87	12/14/87	12/10/87
Units	ug/kg	ug/kg	ug/kg
Blanks or Duplicates		Duplicate	

Chemical	CRQL[a]	Concentration	Qualifer[b]	CRQL[a]	Concentration	Qualifer[b]	CRQL[a]	Concentration	Qualifer[b]
Aroclor-1016	80	80	U	80	80	U	2000[c]	2000	UJ
Aroclor-1221	80	80	U	80	80	U	2000[c]	2000	UJ
Aroclor-1232	80	80	U	80	80	U	2000[c]	2000	UJ
Aroclor-1242	80	40	J	80	42	J	2000[c]	2000	UJ
Aroclor-1248	80	30	J	80	36	J	2000[c]	2000	UJ
Aroclor-1254	160	120	J	160	110	J	2000[c]	1800	J
Aroclor-1260	160	210		160	220		2000[c]	2100	

Note: All values other than qualifiers must be entered as numbers, not as labels.

[a] Contract-required quantitation limit (unless otherwise noted). Values for illustration only.

[b] Refer to Section 5.4 for an explanation of qualifiers.

[c] Sample quantitation limit.

5.2 EVALUATION OF ANALYTICAL METHODS

Group data according to the types of analyses conducted (e.g., field screening analysis, semivolatiles analyzed by EPA methods for water and wastewater, semivolatiles analyzed by EPA's Superfund Contract Laboratory Program [CLP] procedures) to determine which analytical method results are appropriate for use in quantitative risk assessment. Often, this determination has been made already by regional and contractor staff.

An overview of EPA analytical methods is provided in the box below. Exhibit 5-3 presents examples of the types of data that are not usually appropriate for use in quantitative risk assessment, even though they may be available from a site investigation.

OVERVIEW OF THE CLP AND OTHER EPA ANALYTICAL METHODS

The EPA Contract Laboratory Program (CLP) is intended to provide analytical services for Superfund waste site samples. As discussed in the User's Guide to the Contract Laboratory Program (EPA 1988a, hereafter referred to as the CLP User's Guide), the program was developed to fill the need for legally defensible results supported by a high level of quality assurance (i.e., data of known quality) and documentation.

Prior to becoming CLP laboratories, analytical laboratories must meet stringent requirements for laboratory space and practices, instrumentation, personnel training, and quality control (QC), and also must successfully analyze performance evaluation (PE) samples. Before the first samples are shipped to the laboratory, audits of CLP labs are conducted to verify all representations made by laboratory management. Continuing performance is monitored by periodic PE sample analyses, routine and remedial audits, contract compliance screening of data packages, and oversight by EPA.

Superfund samples are most commonly analyzed using the Routine Analytical Services (RAS) conducted by CLP laboratories. Under RAS, all data are generated using the same analytical protocols specifying instrumentation, sample handling, analysis parameters, required quantitation limits, QC requirements, and report format. Protocols are provided in the CLP Statement of Work (SOW) for Inorganics (EPA 1988b) and the CLP Statement of Work for Organics (1988c). The SOWs also contain EPA's target analyte or compound lists (TAL for inorganics, TCL for organics), which are the lists of analytes and required quantitation limits (QLs) for which every Superfund site sample is routinely analyzed under RAS. As of June 1989, analytes on the TCL/TAL consist of 34 volatile organic chemicals (VOCs), 65 semivolatile organic chemicals (SVOCs), 19 pesticides, 7 polychlorinated biphenyls, 23 metals, and total cyanide. Finally, the SOW specifies data qualifiers that may be placed on certain data by the laboratory to communicate information and/or QC problems.

CLP labs are required to submit RAS data packages to EPA's Sample Management Office (SMO) and to the EPA region from which the samples originated within 35 days of receipt of samples. SMO provides management, operational, and administrative support to the CLP to facilitate optimal use of the program. SMO personnel identify incomplete or missing elements and verify compliance with QA/QC requirements in the appropriate SOW. In addition to the SMO review, all CLP data are inspected by EPA-appointed regional data validators. Using Laboratory Data Validation Functional Guidelines issued by EPA headquarters (hereafter referred to as Functional Guidelines for Inorganics [EPA 1988d] and Functional Guidelines for Organics [EPA 1988e]), regional guidelines, and professional judgment, the person validating data identifies deviations from the SOW, poor QC results, matrix interferences, and other analytical problems that may compromise the potential uses of the data. In the validation process, data may be flagged with qualifiers to alert data users of deviations from QC requirements. These qualifiers differ from those qualifiers attached to the data by the laboratory.

In addition to RAS, non-standard analyses may be conducted using Special Analytical Services (SAS) to meet user requirements such as short turnaround time, lower QLs, non-standard matrices, and the testing of analytes other than those on the Target Compound List. Under SAS, the user requests specific analyses, QC procedures, report formats, and timeframe needed.

Examples of other EPA analytical methods include those described in Test Methods for Evaluating Solid Waste (EPA 1986; hereafter referred to as SW-846 Methods) and Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater (EPA 1984; hereafter referred to as EPA 600 Methods). The SW-846 Methods provide analytical procedures to test solid waste to determine if it is a hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA). These methods include procedures for collecting solid waste samples and for determining reactivity, corrosivity, ignitability, composition of waste, and mobility of waste components. The EPA 600 Methods are used in regulatory programs under the Clean Water Act to determine chemicals present in municipal and industrial wastewaters.

EXHIBIT 5-3

EXAMPLES OF THE TYPES OF DATA POTENTIALLY UNSUITABLE FOR A QUANTITATIVE RISK ASSESSMENT

Analytical Instrument or Method	Purpose of Analysis	Analytical Result
HNu Organic Vapor Detector	Health and Safety, Field Screen	Total Organic Vapor
Organic Vapor Analyzer	Health and Safety, Field Screen	Total Organic Vapor
Combustible Gas Indicator	Health and Safety	Combustible Vapors, Oxygen-deficient Atmosphere
Field Gas Chromatography[a]	Field Screen/Analytical Method	Specific Volatile and Semi-volatile Organic Chemicals

[a] Depending on the detector used, this instrument can be sufficiently sensitive to yield adequate data for use in a quantitative risk assessment; however, a confirming analysis by GC/MS should be performed on a subset of the samples in a laboratory prior to use.

Analytical results that are not specific for a particular compound (e.g., total organic carbon [TOC], total organic halogens [TOX]) or results of insensitive analytical methods (e.g., analyses using portable field instruments such as organic vapor analyzers and other field screening methods) may be useful when considering sources of contamination or potential fate and transport of contaminants. These types of analytical results, however, generally are not appropriate for quantitative risk assessment; therefore, the risk assessor may not want to include them in the summary of chemicals of potential concern for the quantitative risk assessment. In addition, the results of analytical methods associated with unknown, few, or no QA/QC procedures should be eliminated from further quantitative use. These types of results, however, may be useful for qualitative discussions of risk in other sections of the risk assessment report.

The outcome of this step is a set of site data that has been developed according to a standard set of sensitive, chemical-specific methods (e.g., SW-846 Methods [EPA 1986], EPA 600 Methods [EPA 1984], CLP Statements of Work [EPA 1988b,c]), with QA/QC procedures that are well-documented and traceable. The data resulting from analyses conducted under the CLP, which generally comprise the majority of results available from a Superfund site investigation, fall into this category.

Although the CLP was developed to ensure that consistent QA/QC methods are used when analyzing Superfund site samples, it does not ensure that all analytical results are consistently of sufficient quality and reliability for use in quantitative risk assessment. Neither the CLP nor QA/QC procedures associated with other methods make judgments concerning the ultimate "usability" of the data. Do not accept at face value all remaining analytical results, whether from the CLP or from some other set of analytical methodologies. Instead, determine -- according to the steps discussed below -- the limitations and uncertainties associated with the data so that only data that are appropriate and reliable for use in a quantitative risk assessment are carried through the process.

5.3 EVALUATION OF QUANTITATION LIMITS

This step involves evaluation of quantitation limits and detection limits (QLs and DLs) for all of the chemicals assessed at the site. This evaluation may lead to the re-analysis of some samples, the use of "proxy" (or estimated) concentrations, and/or the elimination of certain chemicals from further consideration (because they are believed to be absent from the site). Types and definitions of QLs and DLs are presented in the box on the next page.

Before eliminating chemicals because they are not detected (or conducting any other manipulation of the data), the following points should be considered:

(1) the sample quantitation limit (SQL) of a chemical may be greater than corresponding standards, criteria, or concentrations derived from toxicity reference values (and, therefore, the chemical may be present at levels greater than these corresponding reference concentrations, which may result in undetected risk); and

(2) a particular SQL may be significantly higher than positively detected values in other samples in a data set.

These two points are discussed in detail in the following two subsections. A third subsection provides guidance for situations where only some of the samples for a given medium test positive for a particular chemical. A fourth subsection addresses the special situation where SQLs are not available. The final subsection addresses the specific steps involved with elimination of chemicals from the quantitative risk assessment based on their QLs.

5.3.1 SAMPLE QUANTITATION LIMITS (SQLs) THAT ARE GREATER THAN REFERENCE CONCENTRATIONS

As discussed in Chapter 4, QLs needed for the site investigation should be specified in the sampling plan. For some chemicals, however, SQLs obtained under RAS or SAS may exceed

certain reference concentrations (e.g., maximum contaminant levels [MCLs], concentrations corresponding to a 10^{-6} cancer risk). The box on the next page illustrates this problem. For certain chemicals (e.g., antimony), the CLP contract-required quantitation limits (CRQLs) exceed the corresponding reference concentrations for noncarcinogenic effects, based on the EPA-verified reference dose and a 2-liter per day ingestion of water by a 70-kilogram person.[1] Estimation of cancer risks for several other chemicals (e.g., arsenic, styrene) at their CRQLs yields cancer risks exceeding 10^{-4}, based on the same water ingestion factors. Most potential carcinogens with EPA-derived slope factors have CRQLs that yield cancer risk levels exceeding 10^{-6} in water, and none of the carcinogens with EPA-derived slope factors have CRQL values yielding less than 10^{-7} cancer risk levels (as of the publication date of this manual; data not shown).

Three points should be noted when considering this example.

(1) Review of site information and a preliminary determination of chemicals of potential concern at a site prior to sample collection may allow the specification of lower QLs (i.e., using SAS) before an investigation begins (see Chapter 4). This is the most efficient way to minimize the problem of QLs exceeding levels of potential concern.

(2) EPA's Analytical Operations Branch currently is working to reduce the CRQL values for several chemicals on the TCL and TAL, and to develop an analytical service for chemicals with special standards (e.g., MCLs).

TYPES AND DEFINITIONS OF DETECTION LIMITS AND QUANTITATION LIMITS

Strictly interpreted, the detection limit (DL) is the lowest amount of a chemical that can be "seen" above the normal, random noise of an analytical instrument or method. A chemical present below that level cannot reliably be distinguished from noise. DLs are chemical-specific and instrument-specific and are determined by statistical treatment of multiple analyses in which the ratio of the lowest amount observed to the electronic noise level (i.e., the signal-to-noise ratio) is determined. On any given day in any given sample, the calculated limit may not be attainable; however, a properly calculated limit can be used as an overall general measure of laboratory performance.

Two types of DLs may be described -- instrument DLs (IDLs) and method DLs (MDLs). The IDL is generally the lowest amount of a substance that can be detected by an instrument; it is a measure only of the DL for the instrument, and does not consider any effects that sample matrix, handling, and preparation may have. The MDL, on the other hand, takes into account the reagents, sample matrix, and preparation steps applied to a sample in specific analytical methods.

Due to the irregular nature of instrument or method noise, reproducible quantitation of a chemical is not possible at the DL. Generally, a factor of three to five is applied to the DL to obtain a quantitation limit (QL), which is considered to be the lowest level at which a chemical may be accurately and reproducibly quantitated. DLs indicate the level at which a small amount would be "seen," whereas QLs indicate the levels at which measurements can be "trusted."

Two types of QLs may be described -- contract-required QLs (CRQLs) and sample QLs (SQLs). (Contract-required detection limits [CRDL] is the term used for inorganic chemicals. For the purposes of this manual, however, CRQL will refer to both organic and inorganic chemicals.) In order to participate in the CLP, a laboratory must be able to meet EPA CRQLs. CRQLs are chemical-specific and vary depending on the medium analyzed and the amount of chemical expected to be present in the sample. As the name implies, CRQLs are not necessarily the lowest detectable levels achievable, but rather are levels that a CLP laboratory should routinely and reliably detect and quantitate in a variety of sample matrices. A specific sample may require adjustments to the preparation or analytical method (e.g., dilution, use of a smaller sample aliquot) in order to be analyzed. In these cases, the reported QL must in turn be adjusted. Therefore, SQLs, not CRQLs, will be the QLs of interest for most samples. In fact, for the same chemical, a specific SQL may be higher than, lower than, or equal to SQL values for other samples. In addition, preparation or analytical adjustments such as dilution of a sample for quantitation of an extremely high level of only one compound could result in non-detects for all other compounds included as analytes for a particular method, even though these compounds may have been present at trace quantities in the undiluted sample. Because SQLs take into account sample characteristics, sample preparation, and analytical adjustments, these values are the most relevant QLs for evaluating non-detected chemicals.

EXAMPLE OF HEALTH RISKS FROM INGESTION OF WATER CONTAMINATED WITH SELECTED CHEMICALS AT THEIR QUANTITATION LIMITS[a]

Chemical	CAS #	CRQL or CRDL (ug/L)[b]	CRDL/RfC[c]	Cancer Risk at CRQL or CRDL[d]
Antimony	7440-36-0	60	4.3	
Arsenic	7440-38-2	10		$5x10^{-4}$
Benz(a)pyrene	50-32-8	10		$3x10^{-3}$
Bis(2-Chloroethyl)ether	111-44-4	10		$3x10^{-4}$
2,4-Dinitrotoluene	121-14-2	10		$2x10^{-4}$
Hexachlorobenzene	118-74-1	10		$5x10^{-4}$
N-Nitroso-di-n-dipropylamine	621-64-7	10		$2x10^{-3}$
PCB-1254	11096-69-1	1		$2x10^{-4}$[e]
PCB-1260	11096-82-5	1		$2x10^{-4}$
Styrene	100-42-5	5		$4x10^{-4}$
Vinyl chloride	75-01-4	10		$7x10^{-4}$

[a] All values in this example are for illustration purposes only.

[b] CRQL = Contract-required quantitation limit (organics) of the Contract Laboratory Program (revised April 1989).
CRDL = Contract-required detection limit (inorganics) of the Contract Laboratory Program (revised July 1988).

The CRQL and CRDL values presented here are for the regular multi-media multi-concentration CLP methods.

[c] RfC = Reference concentration (based on the August 1989 reference dose for oral exposure, assuming a 70-kilogram adult drinks 2 liters of contaminated water per day).

[d] Cancer Risk at CRQL or CRDL = Excess upper-bound lifetime cancer risk (based on the August 1989 slope factor for oral exposure, assuming a 70-kilogram adult drinks 2 liters of contaminated water per day).

[e] PCB-1260 slope factor was used.

(3) In several situations, an analytical laboratory may be able to attain QLs in particular samples that are below or above the CRQL values.

If SAS was not specified before sampling began and/or if a chemical is not detected in any sample from a particular medium at the QL, then available modeling data, as well as professional judgment, should be used to evaluate whether the chemical may be present above reference concentrations. If the available information indicates the chemical is not present, see Section 5.3.5 for guidance on eliminating chemicals. If there is some indication that the chemical is present, then either re-analyze selected samples using SAS, if time allows, or address the chemical qualitatively. In determining which option is most appropriate for a site, a screening-level risk assessment should be performed by assuming that the chemical is present in the sample at the SQL (see Section 5.3.4 for situations where SQLs are not available). Carry the chemical through the screening risk assessment, essentially conducting the assessment on the SQL for the particular chemical. In this way, the risks that would be posed if the chemical is present at the SQL can be compared with risks posed by other chemicals at the site.

Re-analyze the sample. This (preferred) option discourages elimination of questionable chemicals (i.e., chemicals that may be present below their QL but above a level of potential concern) from the risk assessment. If time allows and a sufficient quantity of the sample is available, submit a SAS request to re-analyze the sample at QLs that are below reference concentrations. The possible outcome of this option is inclusion of chemicals positively detected at levels above

reference concentrations but below the QLs that would normally have been attained under routine analysis of Superfund samples in the CLP program.

Address the chemical qualitatively. A second and less desirable option for a chemical that may be present below its QL (and possibly above its health-based reference concentration) is to eliminate the chemical from the quantitative risk assessment, noting that if the chemical was detected at a lower QL, then its presence and concentration could contribute significantly to the estimated risks.

5.3.2 UNUSUALLY HIGH SQLs

Due to one or more sample-specific problems (e.g., matrix interferences), SQLs for a particular chemical in some samples may be unusually high, sometimes greatly exceeding the positive results reported for the same chemical in other samples from the data set. Even if these SQLs do not exceed health-based standards or criteria, they may still present problems. If the SQLs cannot be reduced by re-analyzing the sample (e.g., through the use of SAS or sample cleaning procedures to remove matrix interferences), exclude the samples from the quantitative risk assessment if they cause the calculated exposure concentration (i.e., the concentration calculated according to guidance in Chapter 6) to exceed the maximum detected concentration for a particular sample set. The box on this page presents an example of how to address a situation with unusually high QLs.

EXAMPLE OF UNUSUALLY HIGH QUANTITATION LIMITS

In this example, concentrations of semivolatile organic chemicals in soils have been determined using the CLP's RAS.

	Concentration (ug/kg)			
Chemical	Sample 1	Sample 2	Sample 3	Sample 4
Phenol	330 U[a]	390	19,000 U	490

[a] U = Compound was analyzed for, but not detected. Value presented (e.g., 330 U) is the SQL.

The QLs presented in this example (i.e., 330 to 19,000 ug/kg) vary widely from sample to sample. SAS would not aid in reducing the unusually high QL of 19,000 ug/kg noted in Sample 3, assuming it was due to unavoidable matrix interferences. In this case, the result for phenol in Sample 3 would be eliminated from the quantitative risk assessment because it would cause the calculated exposure concentrations (from Chapter 6) to exceed the maximum detected concentration (in this case 490 ug/kg). Thus, the data set would be reduced to three samples: the non-detect in Sample 1 and the two detected values in Samples 2 and 4.

5.3.3 WHEN ONLY SOME SAMPLES IN A MEDIUM TEST POSITIVE FOR A CHEMICAL

Most analytes at a site are not positively detected in <u>each</u> sample collected and analyzed. Instead, for a particular chemical the data set generally will contain some samples with positive results and others with non-detected results. The non-detected results usually are reported as SQLs. These limits indicate that the chemical was not measured above certain levels, which may vary from sample to sample. The chemical may be present at a concentration just <u>below</u> the reported quantitation limit, or it may not be present in the sample at all (i.e., the concentration in the sample is zero).

In determining the concentrations most representative of potential exposures at the site (see Chapter 6), consider the positively detected results together with the non-detected results (i.e., the SQLs). If there is reason to believe that the chemical is present in a sample at a concentration below the SQL, use one-half of the SQL as a proxy concentration. The SQL value itself can be used if there is reason to believe the concentration is closer to it than to one-half the SQL. (See the next subsection for situations where SQLs are not available.) Unless site-specific information indicates that a chemical is not likely to be present in a sample, do not substitute the value zero in place of the SQL (i.e., do not assume that a chemical that is not detected at the SQL would not be detected in the sample if the analysis was extremely sensitive). Also, do not simply omit the non-detected results from the risk assessment.

5.3.4 WHEN SQLs ARE NOT AVAILABLE

A fourth situation concerning QLs may sometimes be encountered when evaluating site data. For some sites, data summaries may not provide the SQLs. Instead, MDLs, CRQLs, or even IDLs may have been substituted wherever a chemical was not detected. Sometimes, no detection or quantitation limits may be provided with the data. As a first step in these situations, always attempt to obtain the SQLs, because these are the most appropriate limits to consider when evaluating non-detected chemicals (i.e., they account for sample characteristics, sample preparation, or analytical adjustments that may differ from sample to sample).

If SQLs cannot be obtained, then, for CLP sample analyses, the CRQL should be used as the QL of interest for each non-detected chemical, with the understanding that these limits may overestimate or underestimate the actual SQL. For samples analyzed by methods different from CLP methods, the MDL may be used as the QL, with the understanding that in most cases this will underestimate the SQL (because the MDL is a measure of detection limits only and does not account for sample characteristics or matrix interferences). Note that the IDL should rarely be used for non-detected chemicals since it is a measure only of the detection limit for a particular instrument and does not consider the effect of sample handling and preparation or sample characteristics.

5.3.5 WHEN CHEMICALS ARE NOT DETECTED IN ANY SAMPLES IN A MEDIUM

After considering the discussion provided in the above subsections, generally eliminate those chemicals that have not been detected in any samples of a particular medium. On CLP data reports, these chemicals will be designated in each sample with a U qualifier preceded by the SQL or CRQL (e.g., 10 U). If information exists to indicate that the chemicals are present, they should not be eliminated. For example, if chemicals with similar transport and fate characteristics are detected frequently in soil at a site, and some of these chemicals also are detected frequently in ground water while the others are not detected, then the undetected chemicals are probably present in the ground water and therefore may need to be included in the risk assessment as ground-water contaminants.

The outcome of this step is a data set that only contains chemicals for which positive data (i.e., analytical results for which measurable concentrations are reported) are available in at least one sample from each medium. Unless otherwise indicated, assume at this point in the evaluation of data that positive data to which no uncertainties are attached concerning either the assigned identity of the chemical or the reported concentration (i.e., data that are not "tentative," "uncertain," or "qualitative") are appropriate for use in the quantitative risk assessment.

5.4 EVALUATION OF QUALIFIED AND CODED DATA

For CLP analytical results, various qualifiers and codes (hereafter referred to as qualifiers) are attached to certain data by either the laboratories conducting the analyses or by persons performing data validation. These qualifiers often pertain to QA/QC problems and generally indicate questions concerning chemical identity, chemical concentration, or both. All qualifiers must be addressed before the chemical can be used in quantitative risk assessment. Qualifiers used by the laboratory may differ from those used by data validation personnel in either identity or meaning.

5.4.1 TYPES OF QUALIFIERS

A list of the qualifiers that laboratories are permitted to use under the CLP -- and their potential use in risk assessment -- is presented in Exhibit 5-4. A similar list addressing data validation qualifiers is provided in Exhibit 5-5. In general, because the data validation process is intended to assess the effect of QC issues on data usability, validation data qualifiers are attached to the data after the laboratory qualifiers and supersede the laboratory qualifiers. If data have both laboratory and validation qualifiers and they appear contradictory, ignore the laboratory qualifier and consider only the validation qualifier. If qualifiers have been attached to certain data by the laboratory and have not been removed, revised, or superseded during data validation, then

EXHIBIT 5-4

CLP LABORATORY DATA QUALIFIERS AND THEIR POTENTIAL USE IN QUANTITATIVE RISK ASSESSMENT

Qualifier	Definition	Indicates: Uncertain Identity?	Indicates: Uncertain Concentration?	Include Data in Quantitative Risk Assessment?
Inorganic Chemical Data:[a]				
B	Reported value is <CRDL, but >IDL.	No	?	Yes
U	Compound was analyzed for, but not detected.	Yes	Yes	?
E	Value is estimated due to matrix interferences.	No	Yes	Yes
M	Duplicate injection precision criteria not met.	No	Yes	Yes
N	Spiked sample recovery not within control limits.	No	Yes	Yes
S	Reported value was determined by the Method of Standard Additions (MSA).	No	No	Yes
W	Post-digestion spike for furnace AA analysis is out of control limits, while sample absorbance is <50% of spike absorbance.	No	Yes	Yes
*	Duplicate analysis was not within control limits.	No	Yes	Yes
+	Correlation coefficient for MSA was <0.995.	No	Yes	Yes
Organic Chemical Data:[b]				
U	Compound was analyzed for, but not detected.	Yes	Yes	?

(continued)

EXHIBIT 5-4 (continued)

CLP LABORATORY DATA QUALIFIERS AND THEIR POTENTIAL USE IN QUANTITATIVE RISK ASSESSMENT

Qualifier	Definition	Indicates: Uncertain Identity?	Indicates: Uncertain Concentration?	Include Data in Quantitative Risk Assessment?
J	Value is estimated, either for a tentatively identified compound (TIC) or when a compound is present (spectral identification criteria are met, but the value is <CRQL).	No, for TCL chemicals; Yes, for TICs	Yes	?
C	Pesticide results were confirmed by GC/MS.	No	No	Yes
B	Analyte found in associated blank as well as in sample.[c]	No	Yes	Yes
E	Concentration exceeds calibration range of GC/MS instrument.	No	Yes	Yes
D	Compound identified in an analysis at a secondary dilution factor.	No	No	Yes
A	The TIC is a suspected aldol-condensation product.	Yes	Yes	No
X	Additional flags defined separately.	--	--	--

-- = Data will vary with laboratory conducting analyses.

[a] Source: EPA 1988b.

[b] Source: EPA 1988c.

[c] See Section 5.5 for guidance concerning blank contamination.

EXHIBIT 5-5

VALIDATION DATA QUALIFIERS AND THEIR POTENTIAL USE IN QUANTITATIVE RISK ASSESSMENT

Qualifier	Definition	Indicates: Uncertain Identity?	Indicates: Uncertain Concentration?	Include Data in Quantitative Risk Assessment?
Inorganic and Organic Chemical Data:[a]				
U	The material was analyzed for, but not detected. The associated numerical value is the SQL.	Yes	Yes	?
J	The associated numerical value is an estimated quantity.	No	Yes	Yes
R	Quality control indicates that the data are unusable (compound may or may not be present). Re-sampling and/or re-analysis is necessary for verification.	Yes	Yes	No
Z	No analytical result (inorganic data only).	--	--	--
Q	No analytical result (organic data only).	--	--	--
N	Presumptive evidence of presence of material (tentative identification).[b]	Yes	Yes	?

-- = Not applicable

[a] Source: EPA 1988d,e.

[b] Organic chemical data only.

evaluate the laboratory qualifier itself. If it is unclear whether the data have been validated, contact the appropriate data validation and/or laboratory personnel.

The type of qualifier and other site-specific factors determine how qualified data are to be used in a risk assessment. As seen in Exhibits 5-4 and 5-5, the type of qualifier attached to certain data often indicates how that data should be used in a risk assessment. For example, most of the laboratory qualifiers for both inorganic chemical data and organic chemical data (e.g., J, E, N) indicate uncertainty in the reported concentration of the chemical, but not in its assigned identity. Therefore, these data can be used just as positive data with no qualifiers or codes. In general, include data with qualifiers that indicate uncertainties in concentrations but not in identification.

Examples showing the use of certain qualified data are presented in the next two boxes. The first box addresses the J qualifier, the most commonly encountered data qualifier in Superfund data packages. Basically, the guidance here is to use J-qualified concentrations the same way as positive data that do not have this qualifier. If possible, note potential uncertainties associated with the qualifier, so that if data qualified with a J contribute significantly to the risk, then appropriate caveats can be attached.

EXAMPLE OF J QUALIFIERS

In this example, concentrations of volatile organic chemicals in ground water have been determined using the CLP's RAS.

	Concentration (ug/L)			
Chemical	Sample 1	Sample 2	Sample 3	Sample 4
Tetrachloroethene	14,000 J[a]	40	30 U[b]	20 J

[a] J = The numerical value is an estimated quantity.

[b] U = Compound was analyzed for, but not detected. Value presented (e.g., 30 U) is the SQL.

Tetrachlorethene was detected in three of four samples at concentrations of 14,000 µg/l, 40 µg/l, and 20 ug/l; therefore, these concentrations -- as well as the non-detect -- should be used in determining representative concentrations.

EXAMPLE OF VALIDATED DATA CONTAINING R QUALIFIERS

In this example, concentrations of inorganic chemicals in ground water have been determined using the CLP's RAS.

	Concentration (ug/L)			
Chemical	Sample 1	Sample 2	Sample 3	Sample 4
Manganese	310	500 R[a]	30 UR[b]	500

[a] R = Quality control indicates that the data are unusable (compound may or may not be present).

[b] U = Compound was analyzed for, but not detected. Value presented (e.g., 30 U) is the SQL.

These data have been validated, and therefore the R qualifiers indicate that the person conducting the data validation rejected the data for manganese in Samples 2 and 3. The "UR" qualifier means that manganese was not detected in Sample 3; however, the data validator rejected the non-detected result. Eliminate these two samples so that the data set now consists of only two samples (Samples 1 and 4).

An illustration of the use of R-qualified data is presented in the box in this column. The definition, and therefore the use of the R qualifier, differs depending on whether the data have been validated or not. (Note that the CLP formerly used R as a laboratory qualifier to indicate low spike recovery for inorganics. This has been changed, but older data may still have been qualified by the laboratory with an R.) If it is known that the R data qualifier indicates that the sample result was rejected by the data validation personnel, then this result should be eliminated from the risk assessment; if the R data qualifier was placed on the data to indicate estimated data due to low spike recovery (i.e., the R was placed on the data by the laboratory and

not by the validator), then use the R-qualified data in a manner similar to the use of J-qualified data (i.e., use the R-qualified concentrations the same way as positive data that do not have this qualifier). If possible, note whether the R-qualified data are overestimates or underestimates of actual expected chemical concentrations so that appropriate caveats may be attached if data qualified with an R contribute significantly to the risk.

5.4.2 USING THE APPROPRIATE QUALIFIERS

The information presented in Exhibits 5-4 and 5-5 is based on the most recent EPA guidance documents concerning qualifiers: the SOW for Inorganics and the SOW for Organics (EPA 1988b,c) for laboratory qualifiers, and the Functional Guidelines for Inorganics and the Functional Guidelines for Organics (EPA 1988d,e) for validation qualifiers. The types and definitions of qualifiers, however, may be periodically updated within the CLP program. In addition, certain EPA regions may have their own data qualifiers and associated definitions. These regional qualifiers are generally consistent with the Functional Guidelines, but are designed to convey additional information to data users.

In general, the risk assessor should check whether the information presented in this section is current by contacting the appropriate regional CLP or headquarters Analytical Operations Branch staff. Also, if definitions are not reported with the data, regional contacts should be consulted prior to evaluating qualified data. These variations may affect how data with certain qualifiers should be used in a risk assessment. Make sure that definitions of data qualifiers used in the data set for the site have been reported with the data and are current. Never guess about the definition of qualifiers.

5.5 COMPARISON OF CONCENTRATIONS DETECTED IN BLANKS WITH CONCENTRATIONS DETECTED IN SAMPLES

Blank samples provide a measure of contamination that has been introduced into a sample set either (1) in the field while the samples were being collected or transported to the laboratory or (2) in the laboratory during sample preparation or analysis. To prevent the inclusion of non-site-related contaminants in the risk assessment, the concentrations of chemicals detected in blanks must be compared with concentrations of the same chemicals detected in site samples. Detailed definitions of different types of blanks are provided in the box on the next page.

Blank data should be compared with results from samples with which the blanks are associated. It is often impossible, however, to determine the association between certain blanks and data. In this case, compare the blank data with results from the entire sample data set. Use the guidelines in the following paragraphs when comparing sample concentrations with blank concentrations.

Blanks containing common laboratory contaminants. As discussed in the CLP SOW for Organics (EPA 1988c) and the Functional Guidelines for Organics (EPA 1988e), acetone, 2-butanone (or methyl ethyl ketone), methylene chloride, toluene, and the phthalate esters are considered by EPA to be common laboratory contaminants. In accordance with the Functional Guidelines for Organics (EPA 1988e) and the Functional Guidelines for Inorganics (EPA 1988d), if the blank contains detectable levels of common laboratory contaminants, then the sample results should be considered as positive results only if the concentrations in the sample exceed ten times the maximum amount detected in any blank. If the concentration of a common laboratory contaminant is less than ten times the blank concentration, then conclude that the chemical was not detected in the particular sample and, in accordance with EPA guidance, consider the blank-related concentrations of the chemical to be

TYPES OF BLANKS

Blanks are analytical quality control samples analyzed in the same manner as site samples. They are used in the measurement of contamination that has been introduced into a sample either (1) in the field while the samples were being collected or transported to the laboratory or (2) in the laboratory during sample preparation or analysis. Four types of blanks – trip, field, laboratory calibration, and laboratory reagent (or method) – are described below. A discussion on the water used for the blank also is provided.

Trip Blank. This type of blank is used to indicate potential contamination due to migration of volatile organic chemicals (VOCs) from the air on the site or in sample shipping containers, through the septum or around the lid of sampling vials, and into the sample. A trip blank consists of laboratory distilled, deionized water in a 40-ml glass vial sealed with a teflon septum. The blank accompanies the empty sample bottles to the field as well as the samples returning to the laboratory for analysis; it is not opened until it is analyzed in the lab with the actual site samples. The containers and labels for trip blanks should be the same as the containers and labels for actual samples, thus making the laboratory "blind" to the identity of the blanks.

Field Blank. A field blank is used to determine if certain field sampling or cleaning procedures (e.g., insufficient cleaning of sampling equipment) result in cross-contamination of site samples. Like the trip blank, the field blank is a sample of distilled, deionized water taken to the field with empty sample bottles and is analyzed in the laboratory along with the actual samples. Unlike the trip blank, however, the field blank sample is opened in the field and used as a sample would be (e.g., it is poured through cleaned sampling equipment or it is poured from container to container in the vicinity of a gas-powered pump). As with trip blanks, the field blanks' containers and labels should be the same as for actual samples.

Laboratory Calibration Blank. This type of blank is distilled, deionized water injected directly into an instrument without having been treated with reagents appropriate to the analytical method used to analyze actual site samples. This type of blank is used to indicate contamination in the instrument itself, or possibly in the distilled, deionized water.

Laboratory Reagent or Method Blank. This blank results from the treatment of distilled, deionized water with all of the reagents and manipulations (e.g., digestions or extractions) to which site samples will be subjected. Positive results in the reagent blank may indicate either contamination of the chemical reagents or the glassware and implements used to store or prepare the sample and resulting solutions. Although a laboratory following good laboratory practices will have its analytical processes under control, in some instances method blank contamination cannot be entirely eliminated.

Water Used for Blanks. For all the blanks described above, results are reliable only if the water comprising the blank was clean. For example, if the laboratory water comprising the trip blank was contaminated with VOCs prior to being taken to the field, then the source of VOC contamination in the trip blank cannot be isolated (see laboratory calibration blank).

the quantitation limit for the chemical in that sample. Note that if all samples contain levels of a common laboratory contaminant that are less than ten times the level of contamination noted in the blank, then completely eliminate that chemical from the set of sample results.

Blanks containing chemicals that are not common laboratory contaminants. As discussed in the previously referenced guidance, if the blank contains detectable levels of one or more organic or inorganic chemicals that are not considered by EPA to be common laboratory contaminants (e.g., all other chemicals on the TCL), then consider site sample results as positive only if the concentration of the chemical in the site sample exceeds five times the maximum amount detected in any blank. Treat samples containing less than five times the amount in any blank as non-detects and, in accordance with EPA guidance, consider the blank-related chemical concentration to be the quantitation limit for the chemical in that sample. Again, note that if all samples contain levels of a TCL chemical that are less than five times the level of contamination noted in the blank, then completely eliminate that chemical from the set of sample results.

5.6 EVALUATION OF TENTATIVELY IDENTIFIED COMPOUNDS

Both the identity and reported concentration of a tentatively identified compound (TIC) is questionable (see the box on the next page for background on TICs). Two options for addressing TICs exist, depending on the relative number of TICs compared to non-TICs.

5.6.1 WHEN FEW TICs ARE PRESENT

When only a few TICs are present compared to the TAL and TCL chemicals, and no historical or other site information indicates that either a particular TIC may indeed be present at the site (e.g., because it may be a by-product of a chemical operation conducted when the site was active) or that the estimated concentration may be very high (i.e., the risk would be dominated by the TIC), then generally do not include the TICs in the risk assessment. Otherwise, follow the guidance provided in the next subsection. Consult with the RPM about omitting TICs from the quantitative risk assessment, and document reasons for excluding TICs in the risk assessment report.

TENTATIVELY IDENTIFIED COMPOUNDS

EPA's TCL may be a limited subset of the organic compounds that could actually be encountered at a particular site. Thus, although the CLP RAS requires the laboratory to analyze samples only for compounds on the TCL, the analysis of VOCs and SVOCs may indicate the presence of additional organic compounds not on the TCL. These additional compounds are shown by "peaks" on the chromatograms. (A chromatogram is a paper representation of the response of the instrument to the presence of a compound.) The CLP laboratory must attempt to identify the 30 highest peaks (10 VOCs and 20 SVOCs) using computerized searches of a library containing mass spectra (essentially "fingerprints" for particular compounds). When the mass spectra match to a certain degree, the compound (or general class of compound) is named; however, the assigned identity is in most cases highly uncertain. These compounds are called tentatively identified compounds (TICs).

The CLP SOW provides procedures to obtain a rough estimate of concentration of TICs. These estimates, however, are highly uncertain and could be orders of magnitude higher or lower than the actual concentration. For TICs, therefore, assigned identities may be inaccurate, and quantitation is certainly inaccurate. Due to these uncertainties, TIC information often is not provided with data summaries from site investigations. Additional sampling and analysis under SAS may reduce the uncertainty associated with TICs and, therefore, TIC information should be sought when it is absent from data summaries.

5.6.2 WHEN MANY TICs ARE PRESENT

If many TICs are present relative to the TAL and TCL compounds identified, or if TIC concentrations appear high or site information indicates that TICs are indeed present, then further evaluation of TICs is necessary. If sufficient time is available, use SAS to confirm the identity and to positively and reliably measure the concentrations of TICs prior to their use in the risk assessment. If SAS methods to identify and measure TICs are unavailable, or if there is insufficient time to use SAS, then the TICs should be included as chemicals of potential concern in the risk assessment and the uncertainty in both identity and concentration should be noted (unless information exists to indicate that the TICs are not present).

5.7 COMPARISON OF SAMPLES WITH BACKGROUND

In some cases, a comparison of sample concentrations with background concentrations (e.g., using the geometric mean concentrations of the two data sets) is useful for identifying the non-site-related chemicals that are found at or near the site. If background risk might be a concern, it should be calculated separately from site-related risk. Often, however, the comparison of samples with background is unnecessary because of the low risk usually posed by the background chemicals compared to site-related chemicals.

As discussed in Chapter 4, information collected during the RI can provide information on two types of background chemicals: (1) naturally occurring chemicals that have not been influenced by humans and (2) chemicals that are present due to anthropogenic sources. Either type of background chemical can be either localized or ubiquitous.

Information on background chemicals may have been obtained by the collection of site-specific background samples and/or from other sources (e.g., County Soil Conservation Service surveys, United States Geological Survey [USGS]

reports). As discussed in Chapter 4, background concentrations should be from the site or the vicinity of the site.

5.7.1 USE APPROPRIATE BACKGROUND DATA

Background samples collected during the site investigation should not be used if they were obtained from areas influenced or potentially influenced by the site. Instead, the literature sources mentioned in the previous paragraph may be consulted to determine background levels of chemicals in the vicinity of the site. Care must be taken in using literature sources, because the data contained therein might represent nationwide variation in a particular parameter rather than variation typical of the geographic region or geological setting in which the site is located. For example, a literature source providing concentrations of chemicals in ground water on a national scale may show a wide range of concentrations that is not representative of the variation in concentrations that would be expected at a particular site.

5.7.2 IDENTIFY STATISTICAL METHODS

In cases where background comparisons will be made, any statistical methods that will be used should be identified prior to the collection of samples (see Chapter 4). Guidance documents and reports that are available to aid in background comparison are listed in Section 4.4.3. Prior to conducting the steps discussed in the next two subsections, the RPM should be consulted to determine the type of comparison to be made, if any. Both a justification for eliminating chemicals based on a background comparison and a brief overview of the type of comparison conducted should be included in the risk assessment report.

5.7.3 COMPARE CHEMICAL CONCENTRATIONS WITH NATURALLY OCCURRING LEVELS

As defined previously, naturally occurring levels are levels of chemicals that are present under ambient conditions and that have not been increased by anthropogenic sources. If inorganic chemicals are present at the site at naturally occurring levels, they may be eliminated from the quantitative risk assessment. In some cases, however, background concentrations may present a significant risk, and, while cleanup may or may not eliminate this risk, the background risk may be an important site characteristic to those exposed. The RPM will always have the option to consider the risk posed by naturally occurring background chemicals separately.

In general, comparison with naturally occurring levels is applicable only to inorganic chemicals, because the majority of organic chemicals found at Superfund sites are not naturally occurring (even though they may be ubiquitous). The presence of organic chemicals in background samples collected during a site investigation actually may indicate that the sample was collected in an area influenced by site contamination and therefore does not qualify as a true background sample. Such samples should instead be included with other site samples in the risk assessment. Unless a very strong case can be made for the natural occurrence of an organic chemical, do not eliminate it from the quantitative risk assessment for this reason.

5.7.4 COMPARE CHEMICAL CONCENTRATIONS WITH ANTHROPOGENIC LEVELS

Anthropogenic levels are ambient concentrations resulting from human (non-site) sources. Localized anthropogenic background is often caused by a point source such as a nearby factory. Ubiquitous anthropogenic background is often from nonpoint sources such as automobiles. In general, do not eliminate anthropogenic chemicals because, at many sites, it is extremely difficult to conclusively show at this stage of the site investigation that such chemicals are present at the site due to operations not related to the site or the surrounding area.

Often, anthropogenic background chemicals can be identified and considered separately during or at the end of the risk assessment. These chemicals also can be omitted entirely from the risk assessment, but, as discussed for natural background, they may present a significant risk. Omitting anthropogenic background chemicals from the risk assessment could result in the loss of important information for those potentially exposed.

5.8 DEVELOPMENT OF A SET OF CHEMICAL DATA AND INFORMATION FOR USE IN THE RISK ASSESSMENT

After the evaluation of data is complete as specified in previous sections, a list of the samples (by medium) is made that will be used to estimate exposure concentrations, as discussed in Chapter 6 of this guidance. In addition, as shown in the flowchart in Exhibit 5-1, a list of chemicals of potential concern (also by medium) will be needed for the quantitative risk assessment. This list should include chemicals that were:

(1) positively detected in at least one CLP sample (RAS or SAS) in a given medium, including (a) chemicals with no qualifiers attached (excluding samples with unusually high detection limits), and (b) chemicals with qualifiers attached that indicate known identities but unknown concentrations (e.g., J-qualified data);

(2) detected at levels significantly elevated above levels of the same chemicals detected in associated blank samples;

(3) detected at levels significantly elevated above naturally occurring levels of the same chemicals;

(4) only tentatively identified but either may be associated with the site based on historical information or have been confirmed by SAS; and/or

(5) transformation products of chemicals demonstrated to be present.

Chemicals that were not detected in samples from a given medium (i.e., non-detects) but that may be present at the site also may be included in the risk assessment if an evaluation of the risks potentially present at the detection limit is desired.

5.9 FURTHER REDUCTION IN THE NUMBER OF CHEMICALS (OPTIONAL)

For certain sites, the list of potentially site-related chemicals remaining after quantitation limits, qualifiers, blank contamination, and background have been evaluated may be lengthy. Carrying a large number of chemicals through a quantitative risk assessment may be complex, and it may consume significant amounts of time and resources. The resulting risk assessment report, with its large, unwieldy tables and text, may be difficult to read and understand, and it may distract from the dominant risks presented by the site. In these cases, the procedures discussed in this section -- using chemical classes, frequency of detection, essential nutrient information, and a concentration-toxicity screen -- may be used to further reduce the number of chemicals of potential concern in each medium.

If conducting a risk assessment on a large number of chemicals is feasible (e.g., because of adequate computer capability), then the procedures presented in this section should not be used. Rather, the most important chemicals (e.g., those presenting 99 percent of the risk) -- identified after the risk assessment -- could be presented in the main text of the report, and the remaining chemicals could be presented in the appendices.

5.9.1 CONDUCT INITIAL ACTIVITIES

Several activities must be conducted before implementing any of the procedures described in this section: (1) consult with the RPM; (2) consider how the rationale for the procedure should be documented; (3) examine historical information on the site; (4) consider concentration and toxicity of the chemicals; (5) examine the mobility, persistence, and bioaccumulation potential of the chemicals; (6) consider special exposure routes; (7) consider the treatability of the chemicals; (8) examine applicable or relevant and appropriate requirements (ARARs); and (9) examine the need for the procedures. These activities are described below.

Consultation with the RPM. If a large number of chemicals are of potential concern at

a particular site, the RPM should be consulted. Approval by the RPM must be obtained prior to the elimination of chemicals based on any of these procedures. The concentration-toxicity screen in particular may be needed only in rare instances.

Documentation of rationale. The rationale for eliminating chemicals from the quantitative risk assessment based on the procedures discussed below must be clearly stated in the risk assessment report. This documentation, and its possible defense at a later date, could be fairly resource-intensive. If a continuing need to justify this step is expected, then any plans to eliminate chemicals should be reconsidered.

Historical information. Chemicals reliably associated with site activities based on historical information generally should not be eliminated from the quantitative risk assessment, even if the results of the procedures given in this section indicate that such an elimination is possible.

Concentration and toxicity. Certain aspects of concentration and toxicity of the chemicals also must be considered prior to eliminating chemicals based on the results of these procedures. For example, before eliminating potentially carcinogenic chemicals, the weight-of-evidence classification should be considered in conjunction with the concentrations detected at the site. It may be practical and conservative to retain a chemical that was detected at low concentrations if that chemical is a Group A carcinogen. (As discussed in detail in Chapter 7, the weight-of-evidence classification is an indication of the quality and quantity of data underlying a chemical's designation as a potential human carcinogen.)

Mobility, persistence, and bioaccumulation. Three factors that must be considered when implementing these procedures are the mobility, persistence, and bioaccumulation of the chemicals. For example, a highly volatile (i.e., mobile) chemical such as benzene, a long-lived (i.e., persistent) chemical such as dioxin, or a readily taken-up and concentrated (i.e., bioaccumulated) chemical such as DDT, probably should remain in the risk assessment. These procedures do not explicitly include a mobility, persistence, or bioaccumulation component, and therefore the risk assessor must pay special attention to these factors.

Special exposure routes. For some chemicals, certain exposure routes need to be considered carefully before using these procedures. For example, some chemicals are highly volatile and may pose a significant inhalation risk due to the home use of contaminated water, particularly for showering. The procedures described in this section may not account for exposure routes such as this.

Treatability. Some chemicals are more difficult to treat than others and as a result should remain as chemicals of potential concern because of their importance during the selection of remedial alternatives.

ARARs. Chemicals with ARARs (including those relevant to land ban compliance) usually are not appropriate for exclusion from the quantitative risk assessment based on the procedures in this section. This may, however, depend in part on how the chemicals' site concentrations in specific media compare with their ARAR concentrations for these media.

Need for procedures. Quantitative evaluation of <u>all</u> chemicals of potential concern is the most thorough approach in a risk assessment. In addition, the time required to implement and defend the selection procedures discussed in this section may exceed the time needed to simply carry all the chemicals of potential concern through the risk assessment. Usually, carrying all chemicals of potential concern through the risk assessment will not be a difficult task, particularly given the widespread use of computer spreadsheets to calculate exposure concentrations of chemicals and their associated risks. Although the tables that result may indeed be large, computer spreadsheets significantly increase the ability to evaluate a number of chemicals in a relatively short period of time. For these reasons, the procedures discussed here may be needed only in rare instances. As previously stated, the approval of these procedures by the RPM must be obtained prior to implementing any of these optional screening procedures at a particular site.

5.9.2 GROUP CHEMICALS BY CLASS

At times, toxicity values to be used in characterizing risks are available only for certain chemicals within a chemical class. For example, of the polycyclic aromatic hydrocarbons (PAHs) considered to be potential carcinogens, a slope factor currently is available (i.e., as this manual went to press) for benz(a)pyrene only. In these cases, rather than eliminating the other chemicals within the class from quantitative evaluation because of a lack of toxicity values, it may be useful to group data for such a class of chemicals (e.g., according to structure-activity relationships or other similarities) for consideration in later sections of the risk assessment. For example, the concentrations of only one group of chemicals (e.g., carcinogenic PAHs) would be considered rather than concentrations of each of the seven carcinogenic PAHs currently on the TCL.

To group chemicals by class, concentrations of chemicals within each class are summed according to procedures discussed in Chapter 6 of this guidance. Later in the risk assessment, this chemical class concentration would be used to characterize risk using toxicity values (i.e., RfDs or slope factors) associated with one of the chemicals in the particular class.

Three notes of caution when grouping chemicals should be considered: (1) do not group solely by toxicity characteristics; (2) do not group all carcinogenic chemicals or all noncarcinogenic chemicals without regard to structure-activity or other chemical similarities; and (3) discuss in the risk assessment report that grouping can produce either over- or under-estimates of the true risk.

5.9.3 EVALUATE FREQUENCY OF DETECTION

Chemicals that are infrequently detected may be artifacts in the data due to sampling, analytical, or other problems, and therefore may not be related to site operations or disposal practices. Consider the chemical as a candidate for elimination from the quantitative risk assessment if: (1) it is detected infrequently in one or perhaps two environmental media, (2) it is not detected in any other sampled media or at high concentrations, and (3) there is no reason to believe that the chemical may be present. Available modeling results may indicate whether monitoring data that show infrequently detected chemicals are representative of only their sampling locations or of broader areas. Because chemical concentrations at a site are spatially variable, the risk assessor can use modeling results to project infrequently detected chemical concentrations over broader areas when determining whether the subject chemicals are relevant to the overall risk assessment. Judicious use of modeling to supplement available monitoring data often can minimize the need for the RPM to resort to arbitrarily setting limits on inclusion of infrequently detected chemicals in the risk assessment. Any detection frequency limit to be used (e.g., five percent) should be approved by the RPM prior to using this screen. If, for example, a frequency of detection limit of five percent is used, then at least 20 samples of a medium would be needed (i.e., one detect in 20 samples equals a five percent frequency of detection).

In addition to available monitoring data and modeling results, the risk assessor will need to consider other relevant factors (e.g., presence of sensitive subpopulations) in recommending appropriate site-specific limits on inclusion of infrequently detected chemicals in the quantitative risk assessment. For example, the risk assessor should consider whether the chemical is expected to be present based on historical data or any other relevant information (e.g., known degradation products of chemicals present at the site, modeling results). Chemicals expected to be present should not be eliminated. (See the example of chemicals with similar transport and fate characteristics in Section 5.3.5.)

The reported or modeled concentrations and locations of chemicals should be examined to check for hotspots, which may be especially important for short-term exposures and which therefore should not be eliminated from the risk assessment. Always consider detection of particular chemicals in all sampled media because some media may be sources of contamination for other media. For example, a chemical that is infrequently detected in soil (a potential ground-water contamination source) probably should not be eliminated as a site contaminant if the same chemical is frequently detected in ground water. In addition, infrequently detected chemicals with

concentrations that greatly exceed reference concentrations should not be eliminated.

5.9.4 EVALUATE ESSENTIAL NUTRIENTS

Chemicals that are (1) essential human nutrients, (2) present at low concentrations (i.e., only slightly elevated above naturally occurring levels), and (3) toxic only at very high doses (i.e., much higher than those that could be associated with contact at the site) need not be considered further in the quantitative risk assessment. Examples of such chemicals are iron, magnesium, calcium, potassium, and sodium.

Prior to eliminating such chemicals from the risk assessment, they must be shown to be present at levels that are not associated with adverse health effects. The determination of acceptable dietary levels for essential nutrients, however, often is very difficult. Literature values concerning acceptable dietary levels may conflict and may change fairly often as new studies are conducted. For example, arsenic -- a potential carcinogen -- is considered by some scientists to be an essential nutrient based on animal experiments; however, acceptable dietary levels are not well known (EPA 1988f). Therefore, arsenic should be retained in the risk assessment, even though it may be an essential nutrient at undefined dietary levels. Another example of a nutrient that is difficult to characterize is sodium. Although an essential element in the diet, certain levels of sodium may be associated with blood pressure effects in some sensitive individuals (although data indicating an association between sodium in drinking water and hypertension are inadequate [EPA 1987]).

Another problem with determining acceptable dietary levels for essential nutrients is that nutrient levels often are presented in the literature as concentrations within the human body (e.g., blood levels). To identify an essential nutrient concentration to be used for comparison with concentrations in a particular medium at a site, blood (or other tissue) levels of the chemical from the literature must be converted to concentrations in the media of concern for the site (e.g., soil, drinking water).

For these reasons, it may not be possible to compare essential nutrient concentrations with site concentrations in order to eliminate essential nutrient chemicals. In general, only essential nutrients present at low concentrations (i.e., only slightly elevated above background) should be eliminated to help ensure that chemicals present at potentially toxic concentrations are evaluated in the quantitative risk assessment.

5.9.5 USE A CONCENTRATION-TOXICITY SCREEN

The objective of this screening procedure is to identify the chemicals in a particular medium that -- based on concentration and toxicity -- are most likely to contribute significantly to risks calculated for exposure scenarios involving that medium, so that the risk assessment is focused on the "most significant" chemicals.

Calculate individual chemical scores. Two of the most important factors when determining the potential effect of including a chemical in the risk assessment are its measured concentrations at the site and its toxicity. Therefore, in this screening procedure, each chemical in a medium is first scored according to its concentration and toxicity to obtain a risk factor (see the box below). Separate scores are calculated for each medium being evaluated.

INDIVIDUAL CHEMICAL SCORES

$$Rij = (C_{ij})(T_{ij})$$

where:

R_{ij} = risk factor for chemical i in medium j;

C_{ij} = concentration of chemical i in medium j; and

T_{ij} = toxicity value for chemical i in medium j (i.e., either the slope factor or 1/RfD).

The units for the risk factor R_{ij} depend on the medium being screened. In general, the absolute units do not matter, as long as units among chemicals in a medium are the same. The concentration used in the above equation should be the maximum detected concentration, and toxicity values should be obtained in accordance with the procedures discussed in Chapter 7.

Chemicals without toxicity values cannot be screened using this procedure. Such chemicals should always be discussed in the risk assessment as chemicals of potential concern; they should not be eliminated from the risk assessment. Guidance concerning chemicals without toxicity values is provided in Chapter 7.

For some chemicals, both oral and inhalation toxicity values are available. In these cases, the more conservative toxicity values (i.e., ones yielding the larger risk factor when used in the above equation) usually should be used. If only one exposure route is likely for the medium being evaluated, then the toxicity values corresponding to that exposure route should be used.

Calculate total chemical scores (per medium). Chemical-specific risk factors are summed to obtain the total risk factor for all chemicals of potential concern in a medium (see the box on this page). A separate R_j will be calculated for carcinogenic and noncarcinogenic effects. The ratio of the risk factor for each chemical to the total risk factor (i.e., R_{ij}/R_j) approximates the relative risk for each chemical in medium j.

Eliminate chemicals. After carefully considering the factors discussed previously in this subsection, eliminate from the risk assessment chemicals with R_{ij}/R_j ratios that are very low compared with the ratios of other chemicals in the medium. The RPM may wish to specify a limit for this ratio (e.g., 0.01; a lower fraction would be needed if site risks are expected to be high). A chemical that contributes less than the specified fraction of the total risk factor for each medium would not be considered further in the risk assessment for that medium. Chemicals exceeding the limit would be considered likely to contribute significantly to risks, as calculated in subsequent stages of the risk assessment. This screening procedure could greatly reduce the number of chemicals carried through a risk assessment, because in many cases only a few chemicals contribute significantly to the total risk for a particular medium.

TOTAL CHEMICAL SCORES

$$R_j = R_{1j} + R_{2j} + R_{3j} + \ldots + R_{ij}$$

where:

R_j = total risk factor for medium j; and

$R_{1j} + \ldots + R_{ij}$ = risk factors for chemicals 1 through i in medium j.

The risk factors developed in this screening procedure are to be used only for potential reduction of the number of chemicals carried through the risk assessment and have no meaning outside of the context of the screening procedure. They should not be considered as a quantitative measure of a chemical's toxicity or risk or as a substitute for the risk assessment procedures discussed in Chapters 6, 7, and 8 of this guidance.

5.10 SUMMARY AND PRESENTATION OF DATA

The section of the risk assessment report summarizing the results of the data collection and evaluation should be titled "Identification of Chemicals of Potential Concern" (see Chapter 9). Information in this section should be presented in ways that readily support the calculation of exposure concentrations in the exposure assessment portion of the risk assessment. Exhibits 5-6 and 5-7 present examples of tables to be included in this section of the risk assessment report.

EXHIBIT 5-6

EXAMPLE OF TABLE FORMAT FOR PRESENTING CHEMICALS SAMPLED IN SPECIFIC MEDIA

Table X
Chemicals Sampled in Medium Y
(and in Operable Unit Z, if appropriate)
Name of Site, Location of Site

Chemical	Frequency of Detection[a]	Range of Sample Quantitation Limits (units)	Range of Detected Concentrations (units)	Background Levels
Chemical A	3/25	5 - 50	320 - 4600	100 - 140
* Chemical B	25/25	1 - 32	16 - 72	--

-- = Not available.

* Identified as a chemical of potential concern based on evaluation of data according to procedures described in text of report.

[a] Number of samples in which the chemical was positively detected over the number of samples available.

EXHIBIT 5-7

EXAMPLE OF TABLE FORMAT FOR SUMMARIZING CHEMICALS OF POTENTIAL CONCERN IN ALL MEDIA SAMPLED

Table W
Summary of Chemicals of
Potential Concern at Site X, Location Y
(and in Operable Unit Z, if appropriate)

	Concentration				
Chemical	Soils (mg/kg)	Ground Water (ug/L)	Surface Water (ug/L)	Sediments (ug/kg)	Air (ug/m^3)
Chemical A	5 - 1,100	--	2 - 30	--	--
Chemical B	0.5 - 64	5 - 92	--	100 - 45,000	--
Chemical C	--	15 - 890	50 - 11,000	--	--
Chemical D	2 - 12	--	--	--	0.1 - 940

-- = Not available.

5.10.1 SUMMARIZE DATA COLLECTION AND EVALUATION RESULTS IN TEXT

In the introduction for this section of the risk assessment report, clearly discuss in bullet form the steps involved in data evaluation. If the optional screening procedure described in Section 5.9 was used in determining chemicals of potential concern, these steps should be included in the introduction. If both historical data and current data were used in the data evaluation, state this in the introduction. Any special site-specific considerations in collecting and evaluating the data should be mentioned. General uncertainties concerning the quality associated with either the collection or the analysis of samples should be discussed so that the potential effects of these uncertainties on later sections of the risk assessment can be determined.

In the next part of the report, discuss the samples from each medium selected for use in quantitative risk assessment. Provide information concerning the sample collection methods used (e.g., grab, composite) as well as the number and location of samples. If this information is provided in the RI report, simply refer to the appropriate sections. If any samples (e.g., field screening/analytical samples) were excluded specifically from the quantitative risk assessment prior to evaluating the data, document this along with reasons for the exclusion. Again, remember that such samples, while not used in the quantitative risk assessment, may be useful for qualitative discussions and therefore should not be entirely excluded from the risk assessment.

Discuss the data evaluation either by medium, by medium within each operable unit (if the site is sufficiently large to be divided into specific operable units), or by discrete areas within each medium in an operable unit. For each medium, if several source areas with different types and concentrations of chemicals exist, then the medium-specific discussion for each source area may be separate. Begin the discussion with those media (e.g., wastes, soils) that are potential sources of contamination for other media (e.g., ground water, surface water/sediments). If no samples or data were available for a particular medium, discuss this in the text. For soils data, discuss surface soil results separately from those of subsurface soils. Present ground-water results by aquifer if more than one aquifer was sampled. Discuss surface water/sediment results by the specific surface water body sampled.

For each medium, identify in the report the chemicals for which samples were analyzed, and list the analytes that were detected in at least one sample. If any detected chemicals were eliminated from the quantitative risk assessment based on evaluation of data (i.e., based on evaluation of data quality, background comparisons, and the optional screening procedures, if used), provide reasons for the elimination in the text (e.g., chemical was detected in blanks at similar concentrations to those detected in samples or chemical was infrequently detected).

The final subsection of the text is a discussion of general trends in the data results. For example, the text may mention (1) whether concentrations of chemicals of potential concern in most media were close to the detection limits or (2) trends concerning chemicals detected in more than one medium or in more than one operable unit at the site. In addition, the location of hot spots should be discussed, as well as any noticeable trends apparent from sampling results at different times.

5.10.2 SUMMARIZE DATA COLLECTION AND EVALUATION RESULTS IN TABLES AND GRAPHICS

As shown in Exhibit 5-6, a separate table that includes all chemicals detected in a medium can be provided for each medium sampled at a hazardous waste site or for each medium within an operable unit at a site. Chemicals that have been determined to be of potential concern based on the data evaluation should be designated in the table with an asterisk to the left of the chemical name.

For each chemical, present the frequency of detection in a certain medium (i.e., the number of times a chemical was detected over the total number of samples considered) and the range of detected or quantified values in the samples. Do not present the QL or similar indicator of a minimum level (e.g., <10 mg/L, ND) as the lower end of the range; instead, the lower and upper bound of the range should be the minimum and maximum detected values, respectively. The range

of reported QLs obtained for each chemical in various samples should be provided in a separate column. Note that these QLs should be sample-specific; CRQLs, MDLs, or other types of non-sample-specific values should be provided only when SQLs are not available. Note that the range of QLs would not include any limit values (e.g., unusually high QLs) eliminated based on the guidance in Section 5.3. Finally, naturally occurring concentrations of chemicals used in comparing sample concentrations may be provided in a separate column. The source of these naturally occurring levels should be provided in a footnote. List the identity of the samples used in determining concentrations presented in the table in an appropriate footnote.

The final table in this section is a list of the chemicals of potential concern presented by medium at the site or by medium within each operable unit at the site. A sample table format is presented in Exhibit 5-7.

Another useful type of presentation of chemical concentration data is the isopleth (not shown). This graphic characterizes the monitored or modeled concentrations of chemicals at a site and illustrates the spatial pattern of contamination.

ENDNOTE FOR CHAPTER 5

1. Note that the values in this example are for illustration purposes only. Many CRQLs and CRDLs are in the process of being lowered, and the RfDs and slope factors may have changed.

REFERENCES FOR CHAPTER 5

Environmental Protection Agency (EPA). 1984. Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater (EPA 600 Methods) as presented in 40 CFR Part 136, Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act.

- Used to determine chemicals present in municipal and industrial wastewater as provided under the Clean Water Act. Analytical methods for priority pollutants, including sample preparation, reagents, calibration procedures, QA/QC analytical procedures, and calculations.

Environmental Protection Agency (EPA). 1986. Test Methods for Evaluating Solid Waste (SW-846): Physical/Chemical Methods. Office of Solid Waste.

- Provides analytical procedures to test solid waste to determine if it is a hazardous waste as defined under RCRA. Contains information for collecting solid waste samples and for determining reactivity, corrosivity, ignitability, composition of waste, and mobility of waste components.

Environmental Protection Agency (EPA). 1987. Drinking Water; Proposed Substitution of Contaminants and Proposed List of Additional Substances Which May Require Regulation Under the Safe Drinking Water Act. 52 Federal Register 25720 (July 8, 1987).

Environmental Protection Agency (EPA). 1988a. User's Guide to the Contract Laboratory Program. Office of Emergency and Remedial Response.

- Provides requirements and analytical procedures of the CLP protocols developed from technical caucus recommendations for both organic and inorganic analysis. Contains information on CLP objectives and orientation, CLP structure, description of analytical services, utilization of analytical services, auxiliary support services, and program quality assurance.

Environmental Protection Agency (EPA). 1988b. Contract Laboratory Program Statement of Work for Inorganics Analysis: Multi-media, Multi-concentration. Office of Emergency and Remedial Response. SOW No. 788.

- Provides procedures required by EPA for analyzing hazardous waste disposal site samples (aqueous and solid) for inorganic chemicals (25 elements plus cyanide). Contains analytical, document control, and quality assurance/quality control procedures.

Environmental Protection Agency (EPA). 1988c. Contract Laboratory Program Statement of Work for Organics Analysis: Multi-media, Multi-concentration. Office of Emergency and Remedial Response. SOW No. 288.

- Provides procedures required by EPA for analyzing aqueous and solid hazardous waste samples for 126 volatile, semi-volatile, pesticide, and PCB chemicals. Contains analytical, document control, and quality assurance/quality control procedures.

Environmental Protection Agency (EPA). 1988d. Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analysis. Office of Emergency and Remedial Response.

- Provides guidance in laboratory data evaluation and validation for hazardous waste site samples analyzed under the EPA CLP program. Aids in determining data problems and shortcomings and potential actions to be taken.

Environmental Protection Agency (EPA). 1988e. Laboratory Data Validation Functional Guidelines for Evaluating Organics Analysis (Functional Guidelines for Organics). Office of Emergency and Remedial Response.

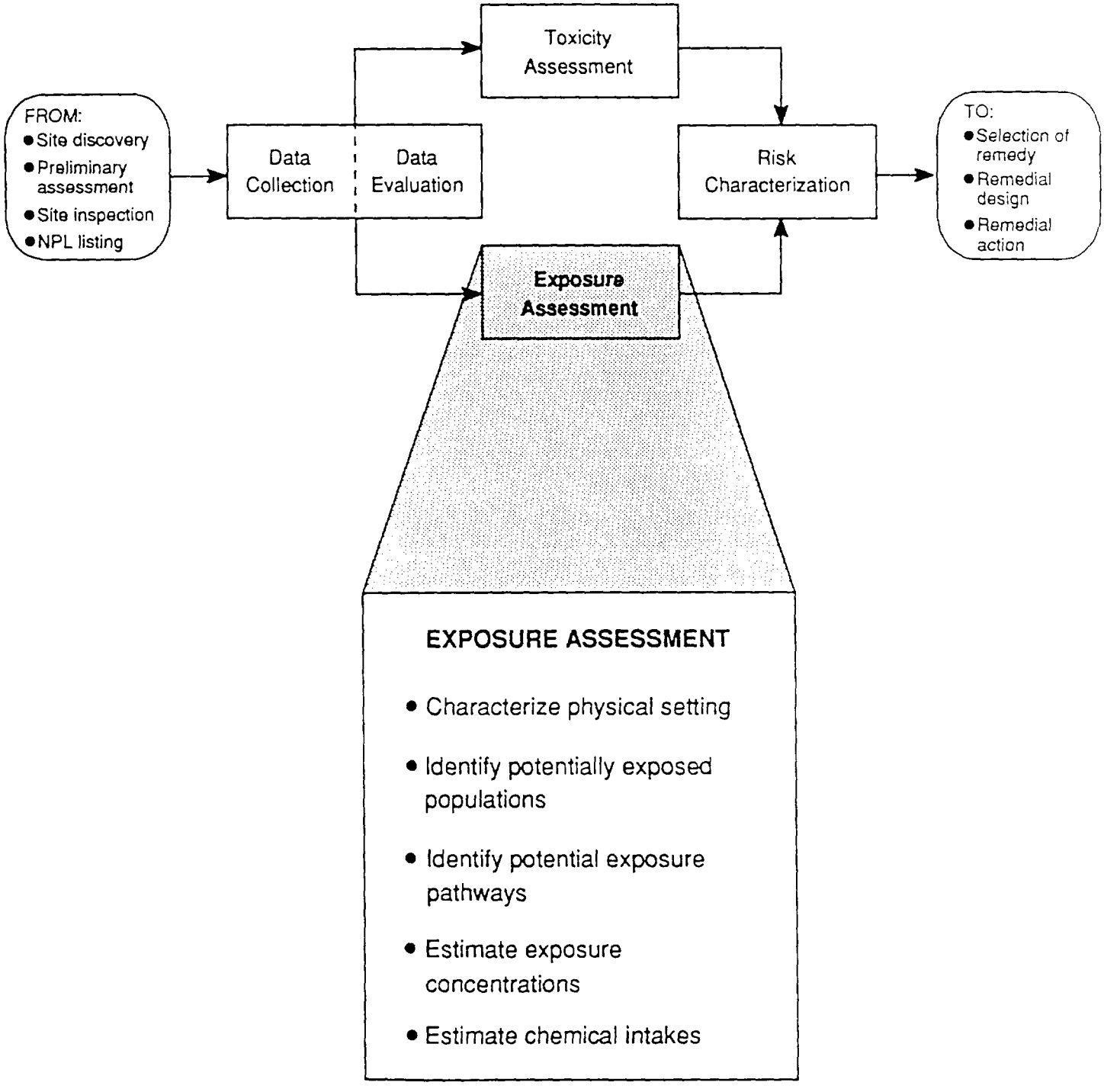
- Provides guidance in laboratory data evaluation and validation for hazardous waste site samples analyzed under the EPA CLP program. Aids in determining data problems and shortcomings and potential actions to be taken.

Environmental Protection Agency (EPA). 1988f. Special Report on Ingested Inorganic Arsenic: Skin Cancer; Nutritional Essentiality. Risk Assessment Forum. EPA 625/3-87/013.

- Technical report concerning the health effects of exposure to ingested arsenic. Includes epidemiologic studies suitable for dose-response evaluation from Taiwan, Mexico, and Germany. Also includes discussions on pathological characteristics and significance of arsenic-induced skin lesions, genotoxicity of arsenic, metabolism and distribution, dose-response estimates for arsenic ingestion and arsenic as an essential nutrient.

CHAPTER 6

EXPOSURE ASSESSMENT



CHAPTER 6

EXPOSURE ASSESSMENT

This chapter describes the procedures for conducting an exposure assessment as part of the baseline risk assessment process at Superfund sites. The objective of the exposure assessment is to estimate the type and magnitude of exposures to the chemicals of potential concern that are present at or migrating from a site. The results of the exposure assessment are combined with chemical-specific toxicity information to characterize potential risks.

The procedures and information presented in this chapter represent some new approaches to exposure assessment as well as a synthesis of currently available exposure assessment guidance and information published by EPA. Throughout this chapter, relevant exposure assessment documents are referenced as sources of more detailed information supporting the exposure assessment process.

6.1 BACKGROUND

Exposure is defined as the contact of an organism (humans in the case of health risk assessment) with a chemical or physical agent (EPA 1988a). The magnitude of exposure is determined by measuring or estimating the amount of an agent available at the exchange boundaries (i.e., the lungs, gut, skin) during a specified time period. Exposure assessment is the determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure. Exposure assessments may consider past, present, and future exposures, using varying assessment techniques for each phase. Estimates of current exposures can be based on measurements or models of existing conditions, those of future exposures can be based on models of future conditions, and those of past exposures can be based on measured or modeled past concentrations or measured chemical concentrations in tissues. Generally, Superfund exposure assessments are concerned with current and future exposures. If human monitoring is planned to assess current or past exposures, the Agency for Toxic Substances and Disease Registry (ATSDR) should be consulted to take the lead in conducting these studies and in assessing the current health status of the people near the site based on the monitoring results.

6.1.1 COMPONENTS OF AN EXPOSURE ASSESSMENT

The general procedure for conducting an exposure assessment is illustrated in Exhibit 6-1. This procedure is based on EPA's published *Guidelines for Exposure Assessment* (EPA 1986a) and on other related guidance (EPA 1988a, 1988b). It is an adaptation of the generalized exposure assessment process to the particular needs of Superfund site risk assessments. Although some exposure assessment activities may have been started earlier (e.g., during RI/FS scoping or even before the RI/FS process began), the detailed exposure assessment process begins after the chemical data have been collected and

ACRONYMS FOR CHAPTER 6

ATSDR = Agency for Toxic Substances and Disease Registry
BCF = Bioconcentration Factor
CDI = Chronic Daily Intake
CEAM = Center for Exposure Assessment Modeling
NOAA = National Oceanographic and Atmospheric Administration
NTGS = National Technical Guidance Studies
OAQPS = Office of Air Quality Planning and Standards
RME = Reasonable Maximum Exposure
SDI = Subchronic Daily Intake
SEAM = Superfund Exposure Assessment Manual
USGS = U.S. Geological Survey

DEFINITIONS FOR CHAPTER 6

Absorbed Dose. The amount of a substance penetrating the exchange boundaries of an organism after contact. Absorbed dose is calculated from the intake and the absorption efficiency. It usually is expressed as mass of a substance absorbed into the body per unit body weight per unit time (e.g., mg/kg-day).

Administered Dose. The mass of a substance given to an organism and in contact with an exchange boundary (e.g., gastrointestinal tract) per unit body weight per unit time (e.g., mg/kg-day).

Applied Dose. The amount of a substance given to an organism, especially through dermal contact.

Chronic Daily Intake (CDI). Exposure expressed as mass of a substance contacted per unit body weight per unit time, averaged over a long period of time (as a Superfund program guideline, seven years to a lifetime).

Contact Rate. Amount of medium (e.g., ground water, soil) contacted per unit time or event (e.g. liters of water ingested per day).

Exposure. Contact of an organism with a chemical or physical agent. Exposure is quantified as the amount of the agent available at the exchange boundaries of the organism (e.g., skin, lungs, gut) and available for absorption.

Exposure Assessment. The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure Event. An incident of contact with a chemical or physical agent. An exposure event can be defined by time (e.g., day, hour) or by the incident (e.g., eating a single meal of contaminated fish).

Exposure Pathway. The course a chemical or physical agent takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of intermedia transfer) also is included.

Exposure Point. A location of potential contact between an organism and a chemical or physical agent.

Exposure Route. The way a chemical or physical agent comes in contact with an organism (i.e., by ingestion, inhalation, dermal contact).

Intake. A measure of exposure expressed as the mass of a substance in contact with the exchange boundary per unit body weight per unit time (e.g., mg chemical/kg-day). Also termed the normalized exposure rate; equivalent to administered dose.

Lifetime Average Daily Intake. Exposure expressed as mass of a substance contacted per unit body weight per unit time, averaged over a lifetime.

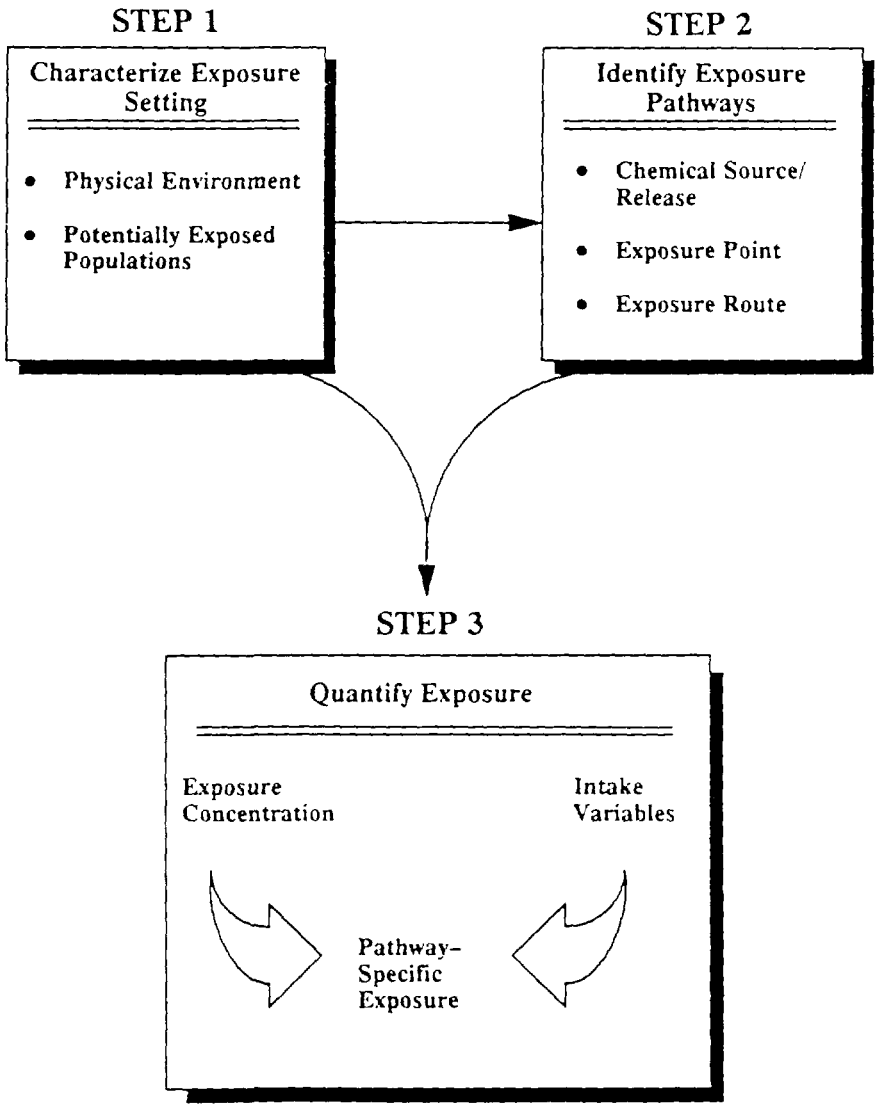
Subchronic Daily Intake (SDI). Exposure expressed as mass of a substance contacted per unit body weight per unit time, averaged over a portion of a lifetime (as a Superfund program guideline, two weeks to seven years).

validated and the chemicals of potential concern have been selected (see Chapter 5, Section 5.3.3). The exposure assessment proceeds with the following steps.

Step 1 -- **Characterization of exposure setting** (Section 6.2). In this step, the assessor characterizes the exposure setting with respect to the general physical characteristics of the site and the characteristics of the populations on and near the site. Basic site characteristics such as climate, vegetation, ground-water hydrology, and the presence and location of surface water are identified in this step. Populations also are identified and are described with respect to those characteristics that influence exposure, such as location relative to the site, activity patterns, and the presence of sensitive subpopulations. This step considers the characteristics of the current population, as well as those of any

EXHIBIT 6-1

THE EXPOSURE ASSESSMENT PROCESS



potential future populations that may differ under an alternate land use.

Step 2 -- Identification of exposure pathways (Section 6.3). In this step, the exposure assessor identifies those pathways by which the previously identified populations may be exposed. Each exposure pathway describes a unique mechanism by which a population may be exposed to the chemicals at or originating from the site. Exposure pathways are identified based on consideration of the sources, releases, types, and locations of chemicals at the site; the likely environmental fate (including persistence, partitioning, transport, and intermedia transfer) of these chemicals; and the location and activities of the potentially exposed populations. Exposure points (points of potential contact with the chemical) and routes of exposure (e.g., ingestion, inhalation) are identified for each exposure pathway.

Step 3 -- Quantification of exposure (Section 6.4). In this step, the assessor quantifies the magnitude, frequency and duration of exposure for each pathway identified in Step 2. This step is most often conducted in two stages: estimation of exposure concentrations and calculation of intakes.

Estimation of exposure concentrations (Section 6.5). In this part of step 3, the exposure assessor determines the concentration of chemicals that will be contacted over the exposure period. Exposure concentrations are estimated using monitoring data and/or chemical transport and environmental fate models. Modeling may be used to estimate future chemical concentrations in media that are currently contaminated or that may become contaminated, and current concentrations in media and/or at locations for which there are no monitoring data.

Calculation of intakes (Section 6.6). In this part of step 3, the exposure assessor calculates chemical-specific exposures for each exposure pathway identified in Step 2. Exposure estimates are expressed in terms of the mass of substance in contact with the body per unit body weight per unit time (e.g., mg chemical per kg body weight per day, also expressed as mg/kg-day). These exposure estimates are termed "intakes" (for the purposes of this manual) and represent the normalized exposure rate. Several terms common in other EPA documents and the literature are equivalent or related to intake (see box on this page and definitions box on page 6-2). Chemical intakes are calculated using equations that include variables for exposure concentration, contact rate, exposure frequency, exposure duration, body weight, and exposure averaging time. The values of some of these variables depend on site conditions and the characteristics of the potentially exposed population.

TERMS EQUIVALENT OR RELATED TO INTAKE

Normalized Exposure Rate. Equivalent to intake

Administered Dose. Equivalent to intake

Applied Dose. Equivalent to intake

Absorbed Dose. Equivalent to intake multiplied by an absorption factor

After intakes have been estimated, they are organized by population, as appropriate (Section 6.7). Then, the sources of uncertainty (e.g., variability in analytical data, modeling results, parameter assumptions) and their effect on the exposure estimates are evaluated and summarized (Section 6.8). This information on uncertainty is important to site decision-makers who must evaluate the results of the exposure and risk assessment and make decisions regarding the degree of remediation required at a site. The exposure assessment concludes with a summary of the estimated intakes for each pathway evaluated (Section 6.9).

6.1.2 REASONABLE MAXIMUM EXPOSURE

Actions at Superfund sites should be based on an estimate of the reasonable maximum exposure (RME) expected to occur under both current and future land-use conditions. The reasonable maximum exposure is defined here as

the highest exposure that is reasonably expected to occur at a site. RMEs are estimated for individual pathways. If a population is exposed via more than one pathway, the combination of exposures across pathways also must represent an RME.

Estimates of the reasonable maximum exposure necessarily involve the use of professional judgment. This chapter provides guidance for determining the RME at a site and identifies some exposure variable values appropriate for use in this determination. The specific values identified should be regarded as general recommendations, and could change based on site-specific information and the particular needs of the EPA remedial project manager (RPM). Therefore, these recommendations should be used in conjunction with input from the RPM responsible for the site.

In the past, exposures generally were estimated for an average and an upper-bound exposure case, instead of a single exposure case (for both current and future land use) as recommended here. The advantage of the two case approach is that the resulting range of exposures provides some measure of the uncertainty surrounding these estimates. The disadvantage of this approach is that the upper-bound estimate of exposure may be above the range of possible exposures, whereas the average estimate is lower than exposures potentially experienced by much of the population. The intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures. Uncertainty is still evaluated under this approach. However, instead of combining many sources of uncertainty into average and upper-bound exposure estimates, the variation in individual exposure variables is used to evaluate uncertainty (See Section 6.8). In this way, the variables contributing most to uncertainty in the exposure estimate are more easily identified.

6.2 STEP 1: CHARACTERIZATION OF EXPOSURE SETTING

The first step in evaluating exposure at Superfund sites is to characterize the site with respect to its physical characteristics as well as those of the human populations on and near the site. The output of this step is a qualitative evaluation of the site and surrounding populations with respect to those characteristics that influence exposure. All information gathered during this step will support the identification of exposure pathways in Step 2. In addition, the information on the potentially exposed populations will be used in Step 3 to determine the values of some intake variables.

6.2.1 CHARACTERIZE PHYSICAL SETTING

Characterize the exposure setting with respect to the general physical characteristics of the site. Important site characteristics include the following:

- climate (e.g., temperature, precipitation);
- meteorology (e.g., wind speed and direction);
- geologic setting (e.g., location and characterization of underlying strata);
- vegetation (e.g., unvegetated, forested, grassy);
- soil type (e.g., sandy, organic, acid, basic);
- ground-water hydrology (e.g., depth, direction and type of flow); and
- location and description of surface water (e.g., type, flow rates, salinity).

Sources of this information include site descriptions and data from the preliminary assessment (PA), site inspection (SI), and remedial investigation (RI) reports. Other sources include county soil surveys, wetlands maps, aerial

photographs, and reports by the National Oceanographic and Atmospheric Association (NOAA) and the U.S. Geological Survey (USGS). The assessor also should consult with appropriate technical experts (e.g., hydrogeologists, air modelers) as needed to characterize the site.

6.2.2 CHARACTERIZE POTENTIALLY EXPOSED POPULATIONS

Characterize the populations on or near the site with respect to location relative to the site, activity patterns, and the presence of sensitive subgroups.

Determine location of current populations relative to the site. Determine the distance and direction of potentially exposed populations from the site. Identify those populations that are closest to or actually living on the site and that, therefore, may have the greatest potential for exposure. Be sure to include potentially exposed distant populations, such as public water supply consumers and distant consumers of fish or shellfish or agricultural products from the site area. Also include populations that could be exposed in the future to chemicals that have migrated from the site. Potential sources of this information include:

- site visit;
- other information gathered as part of the SI or during the initial stages of the RI;
- population surveys conducted near the site;
- topographic, land use, housing or other maps; and
- recreational and commercial fisheries data.

Determine current land use. Characterize the activities and activity patterns of the potentially exposed population. The following land use categories will be applicable most often at Superfund sites:

- residential;
- commercial/industrial; and
- recreational.

Determine the current land use or uses of the site and surrounding area. The best source of this information is a site visit. Look for homes, playgrounds, parks, businesses, industries, or other land uses on or in the vicinity of the site. Other sources on local land use include:

- zoning maps;
- state or local zoning or other land use-related laws and regulations;
- data from the U.S. Bureau of the Census;
- topographic, land use, housing or other maps; and
- aerial photographs.

Some land uses at a site may not fit neatly into one of the three land use categories and other land use classifications may be more appropriate (e.g., agricultural land use). At some sites it may be most appropriate to have more than one land use category.

After defining the land use(s) for a site, identify human activities and activity patterns associated with each land use. This is basically a "common sense" evaluation and is not based on any specific data sources, but rather on a general understanding of what activities occur in residential, business, or recreational areas.

Characterize activity patterns by doing the following.

- Determine the percent of time that the potentially exposed population(s) spend in the potentially contaminated area. For example, if the potentially exposed population is commercial or industrial, a reasonable maximum daily exposure period is likely to be 8 hours (a typical work day). Conversely, if the population is residential, a maximum daily exposure period of 24 hours is possible.
- Determine if activities occur primarily indoors, outdoors, or both. For example,

office workers may spend all their time indoors, whereas construction workers may spend all their time outdoors.

- Determine how activities change with the seasons. For example, some outdoor, summertime recreational activities (e.g., swimming, fishing) will occur less frequently or not at all during the winter months. Similarly, children are likely to play outdoors less frequently and with more clothing during the winter months.

- Determine if the site itself may be used by local populations, particularly if access to the site is not restricted or otherwise limited (e.g., by distance). For example, children living in the area could play onsite, and local residents could hunt or hike onsite.

- Identify any site-specific population characteristics that might influence exposure. For example, if the site is located near major commercial or recreational fisheries or shellfisheries, the potentially exposed population is likely to eat more locally-caught fish and shellfish than populations located inland.

Determine future land use. Determine if any activities associated with a current land use are likely to be different under an alternate future land use. For example, if ground water is not currently used in the area of the site as a source of drinking water but is of potable quality, future use of ground water as drinking water would be possible. Also determine if land use of the site itself could change in the future. For example, if a site is currently classified as industrial, determine if it could possibly be used for residential or recreational purposes in the future.

Because residential land use is most often associated with the greatest exposures, it is generally the most conservative choice to make when deciding what type of alternate land use may occur in the future. However, an assumption of future residential land use may not be justifiable if the probability that the site will support residential use in the future is exceedingly small.

Therefore, determine possible alternate future land uses based on available information and professional judgment. Evaluate pertinent information sources, including (as available):

- master plans (city or county projections of future land use);

- Bureau of the Census projections; and

- established land use trends in the general area and the area immediately surrounding the site (use Census Bureau or state or local reports, or use general historical accounts of the area).

Note that while these sources provide potentially useful information, they should not be interpreted as providing proof that a certain land use will or will not occur.

Assume future residential land use if it seems possible based on the evaluation of the available information. For example, if the site is currently industrial but is located near residential areas in an urban area, future residential land use may be a reasonable possibility. If the site is industrial and is located in a very rural area with a low population density and projected low growth, future residential use would probably be unlikely. In this case, a more likely alternate future land use may be recreational. At some sites, it may be most reasonable to assume that the land use will not change in the future.

There are no hard-and-fast rules by which to determine alternate future land use. The use of professional judgment in this step is critical. Be sure to consult with the RPM about any decision regarding alternate future land use. Support the selection of any alternate land use with a logical, reasonable argument in the exposure assessment chapter of the risk assessment report. Also include a qualitative statement of the likelihood of the future land use occurring.

Identify subpopulations of potential concern. Review information on the site area to determine if any subpopulations may be at increased risk from chemical exposures due to increased sensitivity, behavior patterns that may result in high exposure, and/or current or past exposures from other sources. Subpopulations that may be

more sensitive to chemical exposures include infants and children, elderly people, pregnant and nursing women, and people with chronic illnesses. Those potentially at higher risk due to behavior patterns include children, who are more likely to contact soil, and persons who may eat large amounts of locally caught fish or locally grown produce (e.g., home-grown vegetables). Subpopulations at higher risk due to exposures from other sources include individuals exposed to chemicals during occupational activities and individuals living in industrial areas.

To identify subpopulations of potential concern in the site area, determine locations of schools, day care centers, hospitals, nursing homes, retirement communities, residential areas with children, important commercial or recreational fisheries near the site, and major industries potentially involving chemical exposures. Use local census data and information from local public health officials for this determination.

6.3 STEP 2: IDENTIFICATION OF EXPOSURE PATHWAYS

This section describes an approach for identifying potential human exposure pathways at a Superfund site. An exposure pathway describes the course a chemical or physical agent takes from the source to the exposed individual. An exposure pathway analysis links the sources, locations, and types of environmental releases with population locations and activity patterns to determine the significant pathways of human exposure.

An exposure pathway generally consists of four elements: (1) a source and mechanism of chemical release, (2) a retention or transport medium (or media in cases involving media transfer of chemicals), (3) a point of potential human contact with the contaminated medium (referred to as the exposure point), and (4) an exposure route (e.g., ingestion) at the contact point. A medium contaminated as a result of a past release can be a contaminant source for other media (e.g., soil contaminated from a previous spill could be a contaminant source for ground water or surface water). In some cases, the source itself (i.e., a tank, contaminated soil) is the exposure point, without a release to any other medium. In these latter cases, an exposure pathway consists of (1) a source, (2) an exposure point, and (3) an exposure route. Exhibit 6-2 illustrates the basic elements of each type of exposure pathway.

The following sections describe the basic analytical process for identifying exposure pathways at Superfund sites and for selecting pathways for quantitative analysis. The pathway analysis described below is meant to be a qualitative evaluation of pertinent site and chemical information, and not a rigorous quantitative evaluation of factors such as source strength, release rates, and chemical fate and transport. Such factors are considered later in the exposure assessment during the quantitative determination of exposure concentrations (Section 6.5).

6.3.1 IDENTIFY SOURCES AND RECEIVING MEDIA

To determine possible release sources for a site in the absence of remedial action, use all available site descriptions and data from the PA, SI, and RI reports. Identify potential release mechanisms and receiving media for past, current, and future releases. Exhibit 6-3 lists some typical release sources, release mechanisms, and receiving media at Superfund sites. Use monitoring data in conjunction with information on source locations to support the analysis of past, continuing, or threatened releases. For example, soil contamination near an old tank would suggest the tank (source) ruptured or leaked (release mechanism) to the ground (receiving media). Be sure to note any source that could be an exposure point in addition to a release source (e.g., open barrels or tanks, surface waste piles or lagoons, contaminated soil).

Map the suspected source areas and the extent of contamination using the available information and monitoring data. As an aid in evaluating air sources and releases, Volumes I and II of the National Technical Guidance Studies (NTGS; EPA 1989a,b) should be consulted.

EXHIBIT 6-2

ILLUSTRATION OF EXPOSURE PATHWAYS

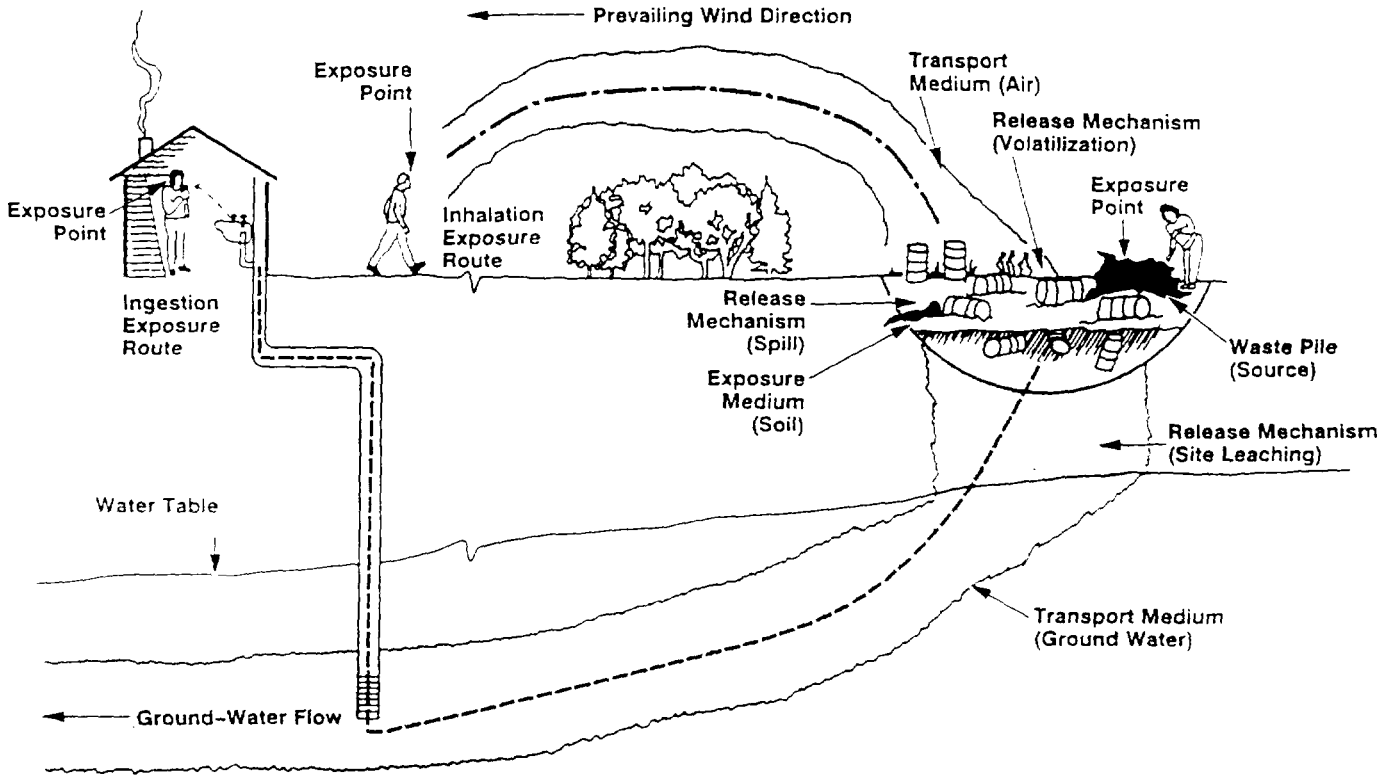


EXHIBIT 6–3

COMMON CHEMICAL RELEASE SOURCES AT SITES IN THE ABSENCE OF REMEDIAL ACTION

Receiving Medium	Release Mechanism	Release Source
Air	Volatilization	Surface wastes — lagoons, ponds, pits, spills Contaminated surface water Contaminated surface soil Contaminated wetlands Leaking drums
	Fugitive dust generation	Contaminated surface soil Waste piles
Surface water	Surface runoff	Contaminated surface soil
	Episodic overland flow	Lagoon overflow Spills, leaking containers
	Ground-water seepage	Contaminated ground water
Ground water	Leaching	Surface or buried wastes Contaminated soil
Soil	Leaching	Surface or buried wastes
	Surface runoff	Contaminated surface soil
	Episodic overland flow	Lagoon overflow Spills, leaking containers
	Fugitive dust generation/ deposition	Contaminated surface soil Waste piles
	Tracking	Contaminated surface soil
Sediment	Surface runoff, Episodic overland flow	Surface wastes — lagoons, ponds, pits, spills Contaminated surface soil
	Ground-water seepage	Contaminated ground water
	Leaching	Surface or buried wastes Contaminated soil
Biota	Uptake (direct contact, ingestion, inhalation)	Contaminated soil, surface water, sediment, ground water or air Other biota

6.3.2 EVALUATE FATE AND TRANSPORT IN RELEASE MEDIA

Evaluate the fate and transport of the chemicals to predict future exposures and to help link sources with currently contaminated media. The fate and transport analysis conducted at this stage of the exposure assessment is not meant to result in a quantitative evaluation of media-specific chemical concentrations. Rather, the intent is to identify media that are receiving or may receive site-related chemicals. At this stage, the assessor should answer the questions: What chemicals occur in the sources at the site and in the environment? In what media (onsite and offsite) do they occur now? In what media and at what location may they occur in the future? Screening-level analyses using available data and simplified calculations or analytical models may assist in this qualitative evaluation.

After a chemical is released to the environment it may be:

- transported (e.g., convected downstream in water or on suspended sediment or through the atmosphere);
- physically transformed (e.g., volatilization, precipitation);
- chemically transformed (e.g., photolysis, hydrolysis, oxidation, reduction, etc.);
- biologically transformed (e.g, biodegradation); and/or
- accumulated in one or more media *(including the receiving medium)*.

To determine the fate of the chemicals of potential concern at a particular site, obtain information on their physical/chemical and environmental fate properties. Use computer data bases (e.g., SRC's Environmental Fate CHEMFATE, and BIODEG data bases; BIOSIS; AQUIRE) and the open literature as necessary as sources for up-to-date information on the physical/chemical and fate properties of the chemicals of potential concern. Exhibit 6-4 lists some important chemical-specific fate parameters and briefly describes how these can be used to evaluate a chemical's environmental fate.

Also consider site-specific characteristics (identified in Section 6.2.1) that may influence fate and transport. For example, soil characteristics such as moisture content, organic carbon content, and cation exchange capacity can greatly influence the movement of many chemicals. A high water table may increase the probability of leaching of chemicals in soil to ground water.

Use all applicable chemical and site-specific information to evaluate transport within and between media and retention or accumulation within a single medium. Use monitoring data to identify media that are contaminated now and the fate pathway analysis to identify media that may be contaminated now (for media not sampled) or in the future. Exhibit 6-5 presents some important questions to consider when developing these pathways. Exhibit 6-6 presents a series of flow charts useful when evaluating the fate and transport of chemicals at a site.

6.3.3 IDENTIFY EXPOSURE POINTS AND EXPOSURE ROUTES

After contaminated or potentially contaminated media have been identified, identify exposure points by determining if and where any of the potentially exposed populations (identified in Step 1) can contact these media. Consider population locations and activity patterns in the area, including those of subgroups that may be of particular concern. Any point of potential contact with a contaminated medium is an exposure point. Try to identify those exposure points where the concentration that will be contacted is the greatest. Therefore, consider including any contaminated media or sources onsite as a *potential exposure point if the site is currently* used, if access to the site under current conditions is not restricted or otherwise limited (e.g., by distance), or if contact is possible under an alternate future land use. For potential offsite exposures, the highest exposure concentrations often will be at the points closest to and downgradient or downwind of the site. In some cases, highest concentrations may be encountered at points distant from the site. For example, site-related chemicals may be transported and deposited in a distant water body where they may be subsequently bioconcentrated by aquatic organisms.

EXHIBIT 6-4

IMPORTANT PHYSICAL/CHEMICAL AND ENVIRONMENTAL FATE PARAMETERS

K_{oc} provides a measure of the extent of chemical partitioning between organic carbon and water at equilibrium. The higher the K_{oc}, the more likely a chemical is to bind to soil or sediment than to remain in water.

K_d provides a soil or sediment-specific measure of the extent of chemical partitioning between soil or sediment and water, unadjusted for dependence upon organic carbon. To adjust for the fraction of organic carbon present in soil or sediment (f_{oc}), use $K_d = K_{oc} x f_{oc}$. The higher the K_d, the more likely a chemical is to bind to soil or sediment than to remain in water.

K_{ow} provides a measure of the extent of chemical partitioning between water and octanol at equilibrium. The greater the K_{ow} the more likely a chemical is to partition to octanol than to remain in water. Octanol is used as a surrogate for lipids (fat), and K_{ow} can be used to predict bioconcentration in aquatic organisms.

Solubility is an upper limit on a chemical's dissolved concentration in water at a specified temperature. Aqueous concentrations in excess of solubility may indicate sorption onto sediments, the presence of solubilizing chemicals such as solvents, or the presence of a non-aqueous phase liquid.

Henry's Law Constant provides a measure of the extent of chemical partitioning between air and water at equilibrium. The higher the Henry's Law constant, the more likely a chemical is to volatilize than to remain in the water.

Vapor Pressure is the pressure exerted by a chemical vapor in equilibrium with its solid or liquid form at any given temperature. It is used to calculate the rate of volatilization of a pure substance from a surface or in estimating a Henry's Law constant for chemicals with low water solubility. The higher the vapor pressure, the more likely a chemical is to exist in a gaseous state.

Diffusivity describes the movement of a molecule in a liquid or gas medium as a result of differences in concentration. It is used to calculate the dispersive component of chemical transport. The higher the diffusivity, the more likely a chemical is to move in response to concentration gradients.

Bioconcentration Factor (BCF) provides a measure of the extent of chemical partitioning at equilibrium between a biological medium such as fish tissue or plant tissue and an external medium such as water. The higher the BCF, the greater the accumulation in living tissue is likely to be.

Media-specific Half-life provides a relative measure of the persistence of a chemical in a given medium, although actual values can vary greatly depending on site-specific conditions. The greater the half-life, the more persistent a chemical is likely to be.

EXHIBIT 6-5

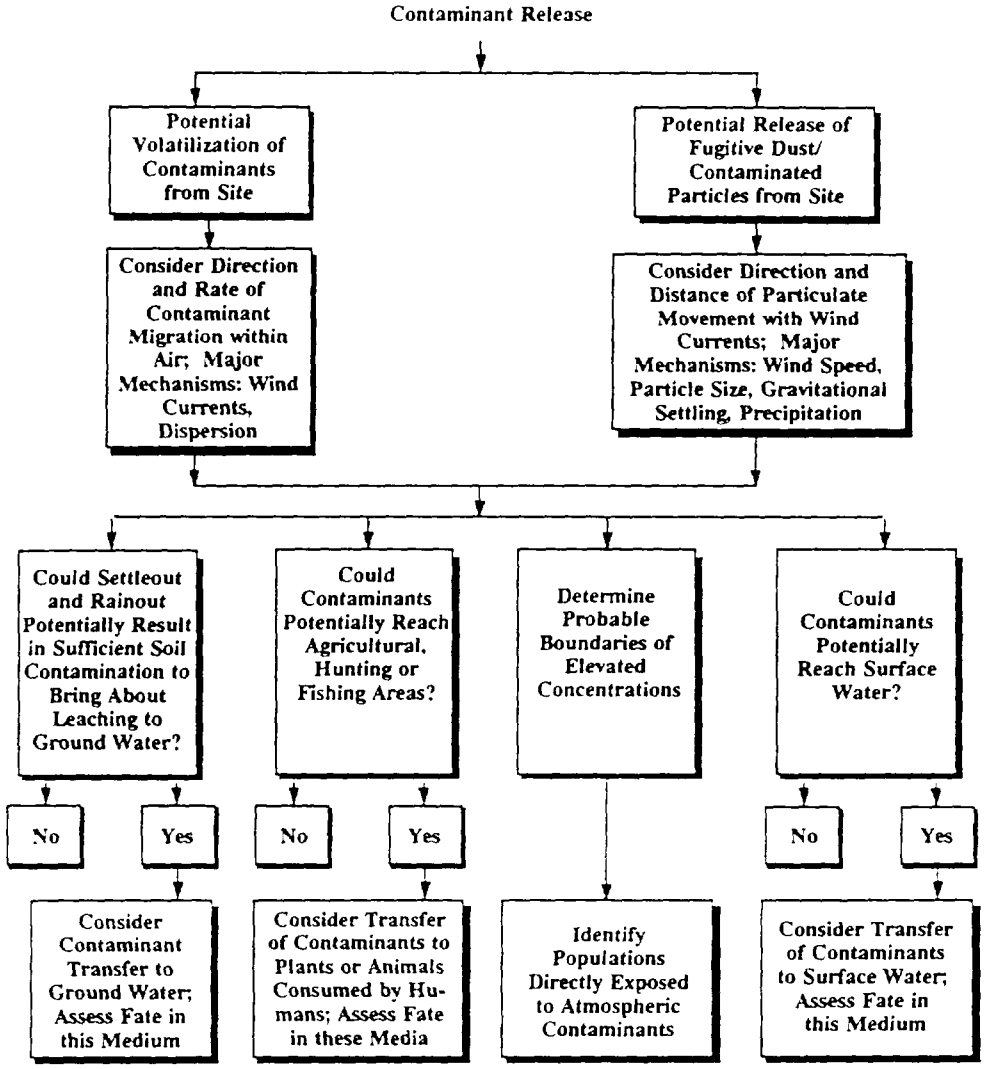
IMPORTANT CONSIDERATIONS FOR DETERMINING THE ENVIRONMENTAL FATE AND TRANSPORT OF THE CHEMICALS OF POTENTIAL CONCERN AT A SUPERFUND SITE

- What are the principal mechanisms for change or removal in each of the environmental media?
- How does the chemical behave in air, water, soil, and biological media? Does it bioaccumulate or biodegrade? Is it absorbed or taken up by plants?
- Does the agent react with other compounds in the environment?
- Is there intermedia transfer? What are the mechanisms for intermedia transfer? What are the rates of the intermedia transfer or reaction mechanism?
- How long might the chemical remain in each environmental medium? How does its concentration change with time in each medium?
- What are the products into which the agent might degrade or change in the environment? Are these products potentially of concern?
- Is a steady-state concentration distribution in the environment or in specific segments of the environment achieved?

EXHIBIT 6-6

FLOW CHART FOR FATE AND TRANSPORT ASSESSMENTS

Environmental fate and transport assessment: atmosphere



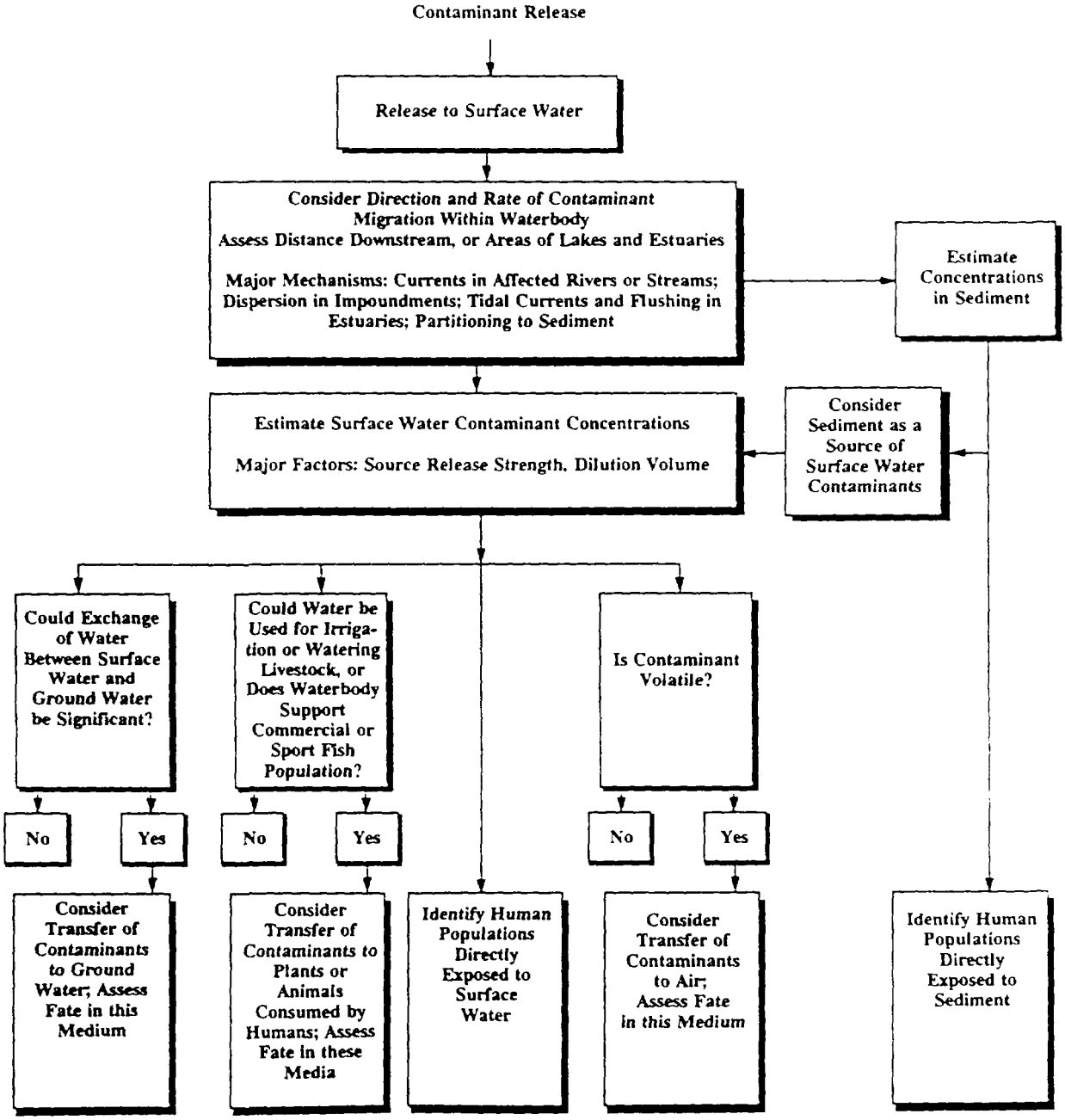
Source: Adapted from EPA 1988b.

(continued)

EXHIBIT 6-6 (continued)

FLOW CHART FOR FATE AND TRANSPORT ASSESSMENTS

Environmental fate and transport assessment: surface water and sediment



Source: Adapted from EPA 1988b.

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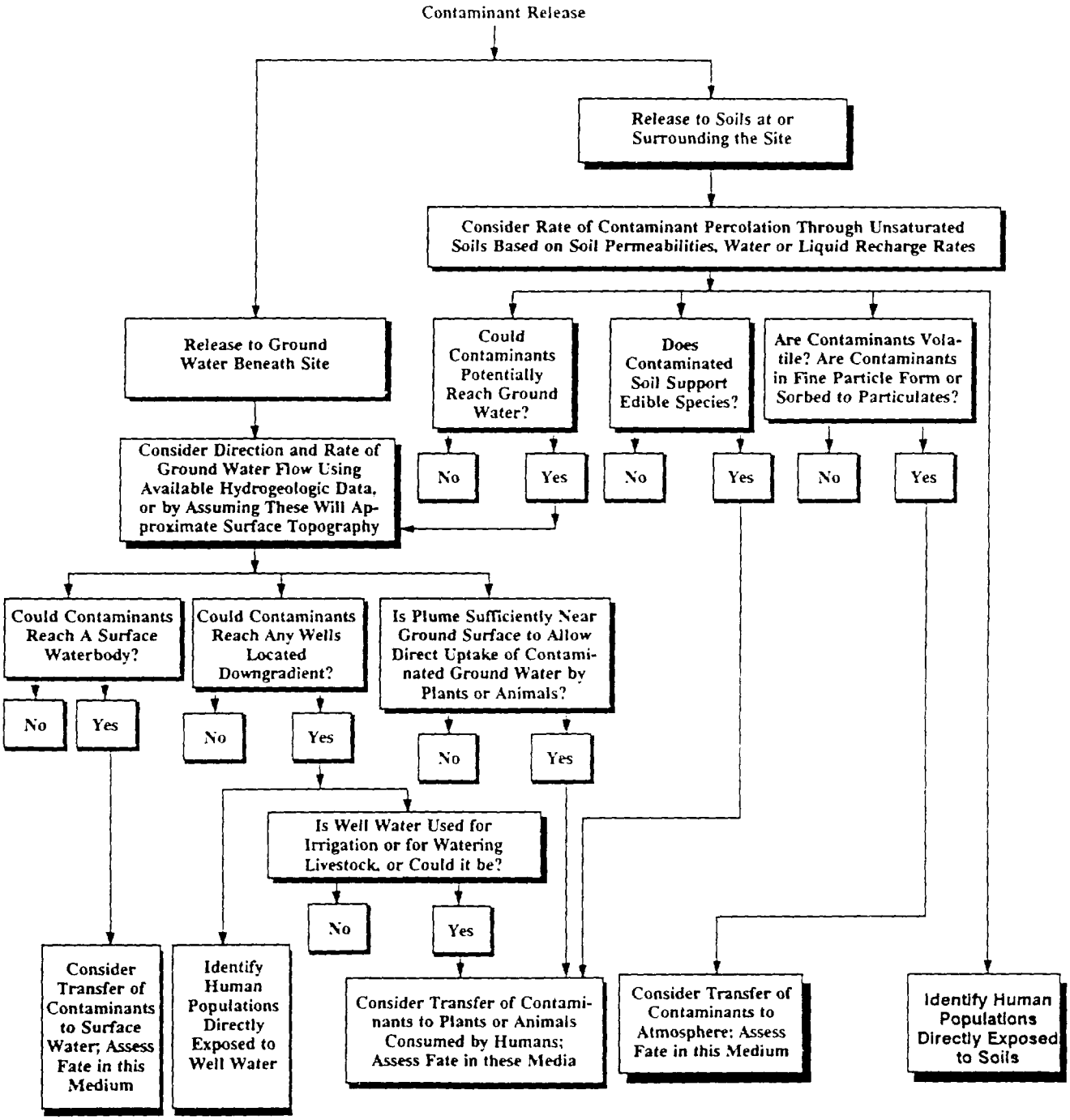
EXHIBIT 6-6 (continued)

FLOW CHART FOR FATE AND TRANSPORT ASSESSMENTS

Environmental fate and transport assessment: soils and ground water



Source: Adapted from EPA 1988b.

After determining exposure points, identify probable exposure routes (i.e., ingestion, inhalation, dermal contact) based on the media contaminated and the anticipated activities at the exposure points. In some instances, an exposure point may exist but an exposure route may not (e.g., a person touches contaminated soil but is wearing gloves). Exhibit 6-7 presents a population/exposure route matrix that can be used in determining potential exposure routes at a site.

6.3.4 INTEGRATE INFORMATION ON SOURCES, RELEASES, FATE AND TRANSPORT, EXPOSURE POINTS, AND EXPOSURE ROUTES INTO EXPOSURE PATHWAYS

Assemble the information developed in the previous three steps and determine the complete exposure pathways that exist for the site. A pathway is complete if there is (1) a source or chemical release from a source, (2) an exposure point where contact can occur, and (3) an exposure route by which contact can occur. Otherwise, the pathway is incomplete, such as the situation where there is a source releasing to air but there are no nearby people. If available from ATSDR, human monitoring data indicating chemical accumulation or chemical-related effects in the site area can be used as evidence to support conclusions about which exposure pathways are complete; however, negative data from such studies should not be used to conclude that a pathway is incomplete.

From all complete exposure pathways at a site, select those pathways that will be evaluated further in the exposure assessment. If exposure to a sensitive subpopulation is possible, select that pathway for quantitative evaluation. All pathways should be selected for further evaluation unless there is sound justification (e.g., based on the results of a screening analysis) to eliminate a pathway from detailed analysis. Such a justification could be based on one of the following:

- the exposure resulting from the pathway is much less than that from another pathway involving the same medium at the same exposure point;
- the potential magnitude of exposure from a pathway is low; or
- the probability of the exposure occurring is very low and the risks associated with the occurrence are not high (if a pathway has catastrophic consequences, it should be selected for evaluation even if its probability of occurrence is very low).

Use professional judgment and experience to make these decisions. Before deciding to exclude a pathway from quantitative analysis, consult with the RPM. If a pathway is excluded from further analysis, clearly document the reasons for the decision in the exposure assessment section of the risk assessment report.

For some complete pathways it may not be possible to quantify exposures in the subsequent steps of the analysis because of a lack of data on which to base estimates of chemical release, environmental concentration, or human intake. Available modeling results should complement and supplement the available monitoring data to minimize such problems. However, uncertainties associated with the modeling results may be too large to justify quantitative exposure assessment in the absence of monitoring data to validate the modeling results. These pathways should nevertheless be carried through the exposure assessment so that risks can be qualitatively evaluated or so that this information can be considered during the uncertainty analysis of the results of the exposure assessment (see Section 6.8) and the risk assessment (see Chapter 8).

6.3.5 SUMMARIZE INFORMATION ON ALL COMPLETE EXPOSURE PATHWAYS

Summarize pertinent information on all complete exposure pathways at the site by identifying potentially exposed populations, exposure media, exposure points, and exposure routes. Also note if the pathway has been selected for quantitative evaluation; summarize the justification if a pathway has been excluded. Summarize pathways for current land use and any alternate future land use separately. This summary information is useful for defining the scope of the next step (quantification of exposure)

EXHIBIT 6-7
MATRIX OF POTENTIAL EXPOSURE ROUTES

Exposure Medium/ Exposure Route	Residential Population	Commercial/Industrial Population	Recreational Population
Ground Water			
Ingestion	L	A	—
Dermal Contact	L	A	—
Surface Water			
Ingestion	L	A	L, C
Dermal Contact	L	A	L, C
Sediment			
Incidental Ingestion	C	A	C
Dermal Contact	C	A	L, C
Air			
Inhalation of Vapor Phase Chemicals			
Indoors	L	A	—
Outdoors	L	A	L
Inhalation of Particulates			
Indoors	L	A	—
Outdoors	L	A	L
Soil/Dust			
Incidental Ingestion	L, C	A	L, C
Dermal Contact	L, C	A	L, C
Food			
Ingestion			
Fish and Shellfish	L	—	L
Meat and Game	L	—	L
Dairy	L, C	—	L
Eggs	L	—	L
Vegetables	L	—	L

L = lifetime exposure
C = exposure in children may be significantly greater than in adults
A = exposure to adults (highest exposure is likely to occur during occupational activities)

— = Exposure of this population via this route is not likely to occur.

and also is useful as documentation of the exposure pathway analysis. Exhibit 6-8 provides a sample format for presenting this information.

6.4 STEP 3: QUANTIFICATION OF EXPOSURE: GENERAL CONSIDERATIONS

The next step in the exposure assessment process is to quantify the magnitude, frequency and duration of exposure for the populations and exposure pathways selected for quantitative evaluation. This step is most often conducted in two stages: first, exposure concentrations are estimated, then, pathway-specific intakes are quantified. The specific methodology for calculating exposure concentrations and pathway-specific exposures are presented in Sections 6.5 and 6.6, respectively. This section describes some of the basic concepts behind these processes.

6.4.1 QUANTIFYING THE REASONABLE MAXIMUM EXPOSURE

Exposure is defined as the contact of an organism with a chemical or physical agent. If exposure occurs over time, the total exposure can be divided by a time period of interest to obtain an average exposure rate per unit time. This average exposure rate also can be expressed as a function of body weight. For the purposes of this manual, exposure normalized for time and body weight is termed "intake", and is expressed in units of mg chemical/kg body weight-day.

Exhibit 6-9 presents a generic equation for calculating chemical intakes and defines the intake variables. There are three categories of variables that are used to estimate intake:

(1) chemical-related variable -- exposure concentration;

(2) variables that describe the exposed population -- contact rate, exposure frequency and duration, and body weight; and

(3) assessment-determined variable -- averaging time.

Each intake variable in the equation has a range of values. For Superfund exposure assessments, intake variable values for a given pathway should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway. As defined previously, the reasonable maximum exposure (RME) is the maximum exposure that is reasonably expected to occur at a site. Under this approach, some intake variables may not be at their individual maximum values but when in combination with other variables will result in estimates of the RME. Some recommendations for determining the values of the individual intake variables are discussed below. These recommendations are based on EPA's determination of what would result in an estimate of the RME. As discussed previously, a determination of "reasonable" cannot be based solely on quantitative information, but also requires the use of professional judgment. Accordingly, the recommendations below are based on a combination of quantitative information and professional judgment. These are general recommendations, however, and could change based on site-specific information or the particular needs of the risk manager. Consult with the RPM before varying from these recommendations.

Exposure concentration. The concentration term in the intake equation is the arithmetic average of the concentration that is contacted over the exposure period. Although this concentration does not reflect the maximum concentration that could be contacted at any one time, it is regarded as a reasonable estimate of the concentration likely to be contacted over time. This is because in most situations, assuming long-term contact with the maximum concentration is not reasonable. (For exceptions to this generalization, see discussion of hot spots in Section 6.5.3.)

Because of the uncertainty associated with any estimate of exposure concentration, the upper confidence limit (i.e., the 95 percent upper confidence limit) on the arithmetic average will be used for this variable. There are standard statistical methods which can be used to calculate the upper confidence limit on the arithmetic mean. Gilbert (1987, particularly sections 11.6 and 13.2) discusses methods that can be applied to data that are distributed normally or log normally. Kriging is another method that

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EXHIBIT 6–8

EXAMPLE OF TABLE FORMAT FOR SUMMARIZING COMPLETE EXPOSURE PATHWAYS AT A SITE

Potentially Exposed Population	Exposure Route, Medium and Exposure Point	Pathway Selected for Evaluation?	Reason for Selection or Exclusion
Current Land Use			
Residents	Ingestion of ground water from local wells down-gradient of the site	Yes	Residents use ground water from local wells as drinking water.
Residents	Inhalation of chemicals volatilized from ground water during home use	Yes	Some of the chemicals of potential concern in ground water are volatile, and ground water is used by local residents.
Industrial Workers	Direct contact with chemicals of potential concern in soil on the site	Yes	Contaminated soil is in an area potentially used by outside maintenance workers.
Future Land Use			
Residents	Direct contact with chemicals of potential concern in soil on the site	Yes	Area could be developed in the future as a residential area.
Residents	Ingestion of chemicals that have accumulated in fish located in onsite ponds	No	The potential for significant exposure via this pathway is low because none of the chemicals of potential concern accumulate extensively in fish.

EXHIBIT 6-9

GENERIC EQUATION FOR CALCULATING CHEMICAL INTAKES

$$I = C \times \frac{CR \times EFD}{BW} \times \frac{1}{AT}$$

Where:

I = intake; the amount of chemical at the exchange boundary (mg/kg body weight-day)

Chemical-related variable

C = chemical concentration; the average concentration contacted over the exposure period (e.g., mg/liter water)

Variables that describe the exposed population

CR = contact rate; the amount of contaminated medium contacted per unit time or event (e.g., liters/day)

EFD = exposure frequency and duration; describes how long and how often exposure occurs. Often calculated using two terms (EF and ED):

EF = exposure frequency (days/year)

ED = exposure duration (years)

BW = body weight; the average body weight over the exposure period (kg)

Assessment-determined variable

AT = averaging time; period over which exposure is averaged (days)

potentially can be used (Clark 1979 is one of several reference books on kriging). A statistician should be consulted for more details or for assistance with specific methods.

If there is great variability in measured or modeled concentration values (such as when too few samples are taken or when model inputs are uncertain), the upper confidence limit on the average concentration will be high, and conceivably could be above the maximum detected or modeled value. In these cases, the maximum detected or modeled value should be used to estimate exposure concentrations. This could be regarded by some as too conservative an estimate, but given the uncertainty in the data in these situations, this approach is regarded as reasonable.

For some sites, where a screening level analysis is regarded as sufficient to characterize potential exposures, calculation of the upper confidence limit on the arithmetic average is not required. In these cases, the maximum detected or modeled concentration should be used as the exposure concentration.

Contact rate. Contact rate reflects the amount of contaminated medium contacted per unit time or event. If statistical data are available for a contact rate, use the 95th percentile value for this variable. (In this case and throughout this chapter, the 90th percentile value can be used if the 95th percentile value is not available.) If statistical data are not available, professional judgment should be used to estimate a value which approximates the 95th percentile value. (It is recognized that such estimates will not be precise. They should, however, reflect a reasonable estimate of an upper-bound value.)

Sometimes several separate terms are used to derive an estimate of contact rate. For example, for dermal contact with chemicals in water, contact rate is estimated by combining information on exposed skin surface area, dermal permeability of a chemical, and exposure time. In such instances, the combination of variables used to estimate intake should result in an estimate approximating the 95th percentile value. Professional judgment will be needed to determine the appropriate combinations of variables. (More specific guidance for determining contact rate for various pathways is given in Section 6.6.)

Exposure frequency and duration. Exposure frequency and duration are used to estimate the total time of exposure. These terms are determined on a site-specific basis. If statistical data are available, use the 95th percentile value for exposure time. In the absence of statistical data (which is usually the case), use reasonable conservative estimates of exposure time. National statistics are available on the upper-bound (90th percentile) and average (50th percentile) number of years spent by individuals at one residence (EPA 1989d). Because of the data on which they are based, these values may underestimate the actual time that someone might live in one residence. Nevertheless, the upper-bound value of 30 years can be used for exposure duration when calculating reasonable maximum residential exposures. In some cases, however, lifetime exposure (70 years by convention) may be a more appropriate assumption. Consult with the RPM regarding the appropriate exposure duration for residential exposures. The exposure frequency and duration selected must be appropriate for the contact rate selected. If a long-term average contact rate (e.g., daily fish ingestion rate averaged over a year) is used, then a daily exposure frequency (i.e., 365 days/year) should be assumed.

Body weight. The value for body weight is the average body weight over the exposure period. If exposure occurs only during childhood years, the average child body weight during the exposure period should be used to estimate intake. For some pathways, such as soil ingestion, exposure can occur throughout the lifetime but the majority of exposure occurs during childhood (because of higher contact rates). In these cases, exposures should be calculated separately for age groups with similar contact rate to body weight ratios; the body weight used in the intake calculation for each age group is the average body weight for that age group. Lifetime exposure is then calculated by taking the time-weighted average of exposure estimates over all age groups. For pathways where contact rate to body weight ratios are fairly constant over a lifetime (e.g., drinking water ingestion), a body weight of 70 kg is used.

A constant body weight over the period of exposure is used primarily by convention, but also because body weight is not always independent of the other variables in the exposure equation (most notably, intake). By keeping body weight

constant, error from this dependence is minimized. The average body weight is used because, when combined with the other variable values in the intake equation, it is believed to result in the best estimate of the RME. For example, combining a 95th percentile contact rate with a 5th percentile body weight is not considered reasonable because it is unlikely that smallest person would have the highest intake. Alternatively, combining a 95th percentile intake with a 95th percentile body weight is not considered a maximum because a smaller person could have a higher contact rate to body weight ratio.

Averaging time. The averaging time selected depends on the type of toxic effect being assessed. When evaluating exposures to developmental toxicants, intakes are calculated by averaging over the exposure event (e.g., a day or a single exposure incident). For acute toxicants, intakes are calculated by averaging over the shortest exposure period that could produce an effect, usually an exposure event or a day. When evaluating longer-term exposure to noncarcinogenic toxicants, intakes are calculated by averaging intakes over the period of exposure (i.e., subchronic or chronic daily intakes). For carcinogens, intakes are calculated by prorating the total cumulative dose over a lifetime (i.e., chronic daily intakes, also called lifetime average daily intake). This distinction relates to the currently held scientific opinion that the mechanism of action for each category is different (see Chapter 7 for a discussion). The approach for carcinogens is based on the assumption that a high dose received over a short period of time is equivalent to a corresponding low dose spread over a lifetime (EPA 1986b). This approach becomes problematic as the exposures in question become more intense but less frequent, especially when there is evidence that the agent has shown dose-rate related carcinogenic effects. In some cases, therefore, it may be necessary to consult a toxicologist to assess the level of uncertainty associated with the exposure assessment for carcinogens. The discussion of uncertainty should be included in both the exposure assessment and risk characterization chapters of the risk assessment report.

6.4.2 TIMING CONSIDERATIONS

At many Superfund sites, long-term exposure to relatively low chemical concentrations (i.e., chronic daily intakes) are of greatest concern. In some situations, however, shorter-term exposures (e.g., subchronic daily intakes) also may be important. When deciding whether to evaluate short-term exposure, the following factors should be considered:

- the toxicological characteristics of the chemicals of potential concern;
- the occurrence of high chemical concentrations or the potential for a large release;
- persistence of the chemical in the environment; and
- the characteristics of the population that influence the duration of exposure.

Toxicity considerations. Some chemicals can produce an effect after a single or very short-term exposure to relatively low concentrations. These chemicals include acute toxicants such as skin irritants and neurological poisons, and developmental toxicants. At sites where these types of chemicals are present, it is important to assess exposure for the shortest time period that could result in an effect. For acute toxicants this is usually a single exposure event or a day, although multiple exposures over several days also could result in an effect. For developmental toxicants, the time period of concern is the exposure event. This is based on the assumption that a single exposure at the critical time in development is sufficient to produce an adverse effect. It should be noted that the critical time referred to can occur in almost any segment of the human population (i.e., fertile men and women, the conceptus, and the child up to the age of sexual maturation [EPA 1989e]).

Concentration considerations. Many chemicals can produce an effect after a single or very short-term exposure, but only if exposure is to a relatively high concentration. Therefore, it is important that the assessor identify possible situations where a short-term exposure to a high concentration could occur. Examples of such a

situation include sites where contact with a small, but highly contaminated area is possible (e.g., a source or a hot spot), or sites where there is a potential for a large chemical release (e.g., explosions, ruptured drums, breached lagoon dikes). Exposure should be determined for the shortest period of time that could produce an effect.

Persistence considerations. Some chemicals may degrade rapidly in the environment. In these cases, exposures should be assessed only for that period of time in which the chemical will be present at the site. Exposure assessments in these situations may need to include evaluations of exposure to the breakdown products, if they are persistent or toxic at the levels predicted to occur at the site.

Population considerations. At some sites, population activities are such that exposure would occur only for a short time period (a few weeks or months), infrequently, or intermittently. Examples of this would be seasonal exposures such as during vacations or other recreational activities. The period of time over which exposures are averaged in these instances depends on the type of toxic effect being assessed (see previous discussion on averaging time, Section 6.4.1).

6.5 QUANTIFICATION OF EXPOSURE: DETERMINATION OF EXPOSURE CONCENTRATIONS

This section describes the basic approaches and methodology for determining exposure concentrations of the chemicals of potential concern in different environmental media using available monitoring data and appropriate models. As discussed in Section 6.4.1, the concentration term in the exposure equation is the average concentration contacted at the exposure point or points over the exposure period. When estimating exposure concentrations, the objective is to provide a conservative estimate of this average concentration (e.g., the 95 percent upper confidence limit on the arithmetic mean chemical concentration).

This section provides an overview of the basic concepts and approaches for estimating exposure concentrations. It identifies what type of information is needed to estimate concentrations, where to find it, and how to interpret and use it. This section is not designed to provide all the information necessary to derive exposure concentrations and, therefore, does not detail the specifics of potentially applicable models nor provide the data necessary to run the models or support concentration estimates. However, sources of such information, including the *Superfund Exposure Assessment Manual* (SEAM; EPA 1988b) are referenced throughout the discussion.

6.5.1 GENERAL CONSIDERATIONS FOR ESTIMATING EXPOSURE CONCENTRATIONS

In general, a great deal of professional judgment is required to estimate exposure concentrations. Exposure concentrations may be estimated by (1) using monitoring data alone, or (2) using a combination of monitoring data and environmental fate and transport models. In most exposure assessments, some combination of monitoring data and environmental modeling will be required to estimate exposure concentrations.

Direct use of monitoring data. Use of monitoring data to estimate exposure concentrations is normally applicable where exposure involves direct contact with the monitored medium (e.g., direct contact with chemicals in soil or sediment), or in cases where monitoring has occurred directly at an exposure point (e.g., a residential drinking water well or public water supply). For these exposure pathways, monitoring data generally provide the best estimate of <u>current</u> exposure concentrations.

As the first step in estimating exposure concentrations, summarize available monitoring data. The manner in which the data are summarized depends upon the site characteristics and the pathways being evaluated. It may be necessary to divide chemical data from a particular medium into subgroups based on the location of sample points and the potential exposure pathways. In other instances, as when the sampling point is an exposure point (e.g., when the sample is from an existing drinking water well)

it may not be appropriate to group samples at all, but may be most appropriate to treat the sample data separately when estimating intakes. Still, in other instances, the assessor may wish to use the maximum concentration from a medium as the exposure concentration for a given pathway as a screening approach to place an upper bound on exposure. In these cases it is important to remember that if a screening level approach suggests a potential health concern, the estimates of exposure should be modified to reflect more probable exposure conditions.

In those instances where it is appropriate to group sampling data from a particular medium, calculate for each exposure medium and each chemical the 95 percent upper confidence limit on the arithmetic average chemical concentration. See Chapter 5 for guidance on how to treat sample concentrations below the quantitation limit.

Modeling approaches. In some instances, it may not be appropriate to use monitoring data alone, and fate and transport models may be required to estimate exposure concentrations. Specific instances where monitoring data alone may not be adequate are as follows.

- Where exposure points are spatially separate from monitoring points. Models may be required when exposure points are remote from sources of contamination if mechanisms for release and transport to exposure points exist (e.g., ground-water transport, air dispersion).

- Where temporal distribution of data is lacking. Typically, data from Superfund investigations are collected over a relatively short period of time. This generally will give a clear indication of current site conditions, but both long-term and short-term exposure estimates usually are required in Superfund exposure assessments. Although there may be situations where it is reasonable to assume that concentrations will remain constant over a long period of time, in many cases the time span of the monitoring data is not adequate to predict future exposure concentrations. Environmental models may be required to make these predictions.

- Where monitoring data are restricted by the limit of quantitation. Environmental models may be needed to predict concentrations of contaminants that may be present at concentrations that are below the quantitation limit but that may still cause toxic effects (even at such low concentrations). For example, in the case of a ground-water plume discharging into a river, the dilution afforded by the river may be sufficient to reduce the concentration of the chemical to a level that could not be detected by direct monitoring. However, as discussed in Section 5.3.1, the chemical may be sufficiently toxic or bioaccumulative that it could present a health risk at concentrations below the limit of quantitation. Models may be required to make exposure estimates in these types of situations.

A wide variety of models are available for use in exposure assessments. SEAM (EPA 1988b) and the *Exposure Assessment Methods Handbook* (EPA 1989f) describe some of the models available and provide guidance in selecting appropriate modeling techniques. Also, the Center for Exposure Assessment Modeling (CEAM -- Environmental Research Laboratory (ERL) Athens), the Source Receptor Analysis Branch (Office of Air Quality Planning and Standards, or OAQPS), and modelers in EPA regional offices can provide assistance in selecting appropriate models. Finally, Volume IV of the NTGS (EPA 1989c) provides guidance for air and atmospheric dispersion modeling for Superfund sites. Be sure to discuss the fate and transport models to be used in the exposure assessment with the RPM.

The level of effort to be expended in estimating exposure concentrations will depend on the type and quantity of data available, the level of detail required in the assessment, and the resources available for the assessment. In general, estimating exposure concentrations will involve analysis of site monitoring data and application of simple, screening-level analytical models. The most important factor in determining the level of

effort will be the quantity and quality of the available data. In general, larger data sets will support the use of more sophisticated models.

Other considerations. When evaluating chemical contamination at a site, it is important to review the spatial distribution of the data and evaluate it in ways that have the most relevance to the pathway being assessed. In short, consider where the contamination is with respect to known or anticipated population activity patterns. Maps of both concentration distribution and activity patterns will be useful for the exposure assessment. It is the intersection of activity patterns and contamination that defines an exposure area. Data from random sampling or from systematic grid pattern sampling may be more representative of a given exposure pathway than data collected only from hot spots.

Generally, verified GC/MS laboratory data with adequate quality control will be required to support quantitative exposure assessment. Field screening data generally cannot be incorporated when estimating exposure concentrations because they are derived using less sensitive analytical methods and are subject to less stringent quality control.

Other areas to be considered in estimating exposure concentrations are as follows.

- Steady-state vs. non-steady-state conditions. Frequently, it may be necessary to assume steady-state conditions because the information required to estimate non-steady-state conditions (such as source depletion rate) is not readily available. This is likely to overestimate long-term exposure concentrations for certain pathways.

- Number and type of exposure parameters that must be assumed. In developing exposure models, values for site-specific parameters such as hydraulic conductivity, organic carbon content of soil, wind speed and direction, and soil type may be required. These values may be generated as part of the RI. In cases where these values are not available, literature values may be substituted. In the absence of applicable literature values, the assessor must consider if a reliable exposure concentration estimate can be made.

- Number and type of fate processes to be considered. In some cases, exposure modeling may be limited to considerations of mass balance, dilution, dispersion, and equilibrium partitioning. In other cases, models of more complex fate processes, such as chemical reaction, biodegradation, and photolysis may be needed. However, prediction of such fate processes requires significantly larger quantities of model calibration and validation data than required for less complex fate processes. For those sites where these more complex fate processes need to be modeled, be sure to consult with the RPM regarding the added data requirements.

6.5.2 ESTIMATE EXPOSURE CONCENTRATIONS IN GROUND WATER

Exposure concentrations in ground water can be based on monitoring data alone or on a combination of monitoring and modeling. In some cases, the exposure assessor may favor the use of monitoring data over the use of complex models to develop exposure concentrations. It is most appropriate to use ground-water sampling data as estimates of exposure concentrations when the sampling points correspond to exposure points, such as samples taken from a drinking water tap. However, samples taken directly from a domestic well or drinking water tap should be interpreted cautiously. For example, where the water is acidic, inorganic chemicals such as lead or copper may leach from the distribution system. Organic chemicals such as phthalates may migrate into water from plastic piping. Therefore, interpretations of these data should consider the type and operation of the pumping, storage, and distribution system involved.

Most of the time, data from monitoring wells will be used to estimate chemical concentrations at the exposure point. Several issues should be considered when using monitoring well data to estimate these concentrations. First, determine if the aquifer has sufficient production capacity and

is of sufficient quality to support drinking water or other uses. If so, it generally should be assumed that water could be drawn from anywhere in the aquifer, regardless of the location of existing wells relative to the contaminant plume. In a few situations, however, it may not be reasonable to assume that water will be drawn from directly beneath a specific source (e.g., a waste management unit such as a landfill) in the future. In these cases, it should be assumed that water could be drawn from directly adjacent to the source. Selection of the location(s) used to evaluate future ground-water exposures should be made in consultation with the RPM. Second, compare the construction of wells (e.g., drinking water wells) in the area with the construction of the monitoring wells. For example, drinking water wells may draw water from more than one aquifer, whereas individual monitoring wells are usually screened in a specific aquifer. In some cases it may be appropriate to separate data from two aquifers that have very limited hydraulic connection if drinking water wells in the area draw water from only one of them. Consult a hydrogeologist for assistance in the above considerations.

Another issue to consider is filtration of water samples. While filtration of ground-water samples provides useful information for understanding chemical transport within an aquifer (see Section 4.5.3 for more details), the use of filtered samples for estimating exposure is very controversial because these data may underestimate chemical concentrations in water from an unfiltered tap. Therefore, data from unfiltered samples should be used to estimate exposure concentrations. Consult with the RPM before using data from filtered samples.

Ground-water monitoring data are often of limited use for evaluating long-term exposure concentrations because they are generally representative of current site conditions and not long-term trends. Therefore, ground-water models may be needed to estimate exposure concentrations. Monitoring data should be used when possible to calibrate the models.

Estimating exposure concentrations in ground water using models can be a complex task because of the many physical and chemical processes that may affect transport and transformation in ground water. Among the important mechanisms that should be considered when estimating exposure concentrations in ground water are leaching from the surface, advection (including infiltration, flow through the unsaturated zone, and flow with ground water), dispersion, sorption (including adsorption, desorption, and ion exchange), and transformation (including biological degradation, hydrolysis, oxidation, reduction, complexation, dissolution, and precipitation). Another consideration is that not all chemicals may be dissolved in water, but may be present instead in nonaqueous phases that float on top of ground water or sink to the bottom of the aquifer.

The proper selection and application of soil and ground-water models requires a thorough understanding of the physical, chemical, and hydrogeologic characteristics of the site. SEAM (EPA 1988b) provides a discussion of the factors controlling soil and ground-water contaminant migration as well as descriptions of various soil and ground-water models. For more in-depth guidance on the selection and application of appropriate ground-water models, consult *Selection Criteria for Mathematical Models Used in Exposure Assessments: Ground-water Models* (EPA 1988c). As with all modeling, the assessor should carefully evaluate the applicability of the model to the site being evaluated, and should consult with a hydrogeologist as necessary.

If ground-water modeling is not used, current concentrations can be used to represent future concentrations in ground water assuming steady-state conditions. This assumption should be noted in the exposure assessment chapter and in the uncertainties and conclusions of the risk assessment.

6.5.3 ESTIMATE EXPOSURE CONCENTRATIONS IN SOIL

Estimates of current exposure concentrations in soil can be based directly on summarized monitoring data if it is assumed that concentrations remain constant over time. Such an assumption may not be appropriate for some chemicals and some sites where leaching, volatilization, photolysis, biodegradation, wind erosion, and surface runoff will reduce chemical concentrations over time. Soil monitoring data and site conditions should be carefully screened to

identify situations where source depletion is likely to be important. SEAM (EPA 1988b) gives steady-state equations for estimating many of these processes. However, incorporating these processes into the calculation of exposure concentrations for soil involves considerable effort. If a modeling approach is not adopted in these situations, assume a constant concentration over time and base exposure concentrations on monitoring data. This assumption should be clearly documented.

In evaluating monitoring data for the assessment of soil contact exposures, the spatial distribution of the data is a critical factor. The spatial distribution of soil contamination can be used as a basis for estimating the average concentrations contacted over time if it is assumed that contact with soil is spatially random (i.e., if contact with soil in all areas of the site is equally probable). Data from random sampling programs or samples from evenly spaced grid networks generally can be considered as representative of concentrations across the site. At many sites however, sampling programs are designed to characterize only obviously contaminated soils or hot spot areas. Care must be taken in evaluating such data sets for estimating exposure concentrations. Samples from areas where direct contact is not realistic (such as where a steep slope or thick vegetation prevents current access) should not be considered when estimating current exposure concentrations for direct contact pathways. Similarly, the depth of the sample should be considered; surface soil samples should be evaluated separately from subsurface samples if direct contact with surface soil or inhalation of wind blown dust are potential exposure pathways at the site.

In some cases, contamination may be unevenly distributed across a site, resulting in hot spots (areas of high contamination relative to other areas of the site). If a hot spot is located near an area which, because of site or population characteristics, is visited or used more frequently, exposure to the hot spot should be assessed separately. The area over which the activity is expected to occur should be considered when averaging the monitoring data for a hot spot. For example, averaging soil data over an area the size of a residential backyard (e.g., an eighth of an acre) may be most appropriate for evaluating residential soil pathways.

6.5.4 ESTIMATE EXPOSURE CONCENTRATIONS IN AIR

There are three general approaches to estimating exposure concentrations in air: (1) ambient air monitoring, (2) emission measurements coupled with dispersion modeling, and (3) emission modeling coupled with dispersion modeling. Whichever approach is used, the resulting exposure concentrations should be as representative as possible of the specific exposure pathways being evaluated. If long-term exposures are being evaluated, the exposure concentrations should be representative of long-term averages. If short-term exposures are of interest, measured or modeled peak concentrations may be most representative.

If monitoring data have been collected at a site, their adequacy for use in a risk assessment should be evaluated by considering how appropriate they are for the exposures being addressed. Volume II of the NTGS (EPA 1989b) provides guidance for measuring emissions and should be consulted when evaluating the appropriateness of emission data. See Chapter 4 (Section 4.5.5) for factors to consider when evaluating the appropriateness of ambient air monitoring data. As long as there are no significant analytical problems affecting air sampling data, background levels are not significantly higher than potential site-related levels, and site-related levels are not below the instrument detection limit, air monitoring data can be used to derive exposure concentrations. There still will be uncertainties inherent in using these data because they usually are not representative of actual long-term average air concentrations. This may be because there were only a few sample collection periods, samples were collected during only one type of meteorological or climatic condition, or because the source of the chemicals will change over time. These uncertainties should be mentioned in the risk assessment.

In the absence of monitoring data, exposure concentrations often can be estimated using models. Two kinds of models are used to estimate air concentrations: emission models that predict the rate at which chemicals may be released into the air from a source, and dispersion models that predict associated concentrations in air at potential receptor points.

Outdoor air modeling. Emissions may occur as a result of the volatilization of chemicals from contaminated media or as a result of the suspension of onsite soils. Models that predict emission rates for volatile chemicals or dust require numerous input parameters, many of which are site-specific. For volatile chemicals, emission models for surface water and soil are available in SEAM (EPA 1988b). Volume IV of the NTGS (EPA 1989c) also provides guidance for evaluating volatile emissions at Superfund sites. Emissions due to suspension of soils may result from wind erosion of exposed soil particles and from vehicular disturbances of the soil. To predict soil or dust emissions, EPA's fugitive dust models provided in AP42 (EPA 1985b) or models described in SEAM (1988b) may be used. Volume IV of the NTGS (EPA 1989c) also will be useful in evaluating fugitive dust emissions at Superfund sites. Be sure to critically review all models before use to determine their applicability to the situation and site being evaluated. If necessary, consult with air modelers in EPA regional offices, the Exposure Assessment Group in EPA headquarters or the Source Receptor Analysis Branch in OAQPS.

After emissions have been estimated or measured, air dispersion models can be applied to estimate air concentrations at receptor points. In choosing a dispersion model, factors that must be considered include the type of source and the location of the receptor relative to the source. For area or point sources, EPA's Industrial Source Complex model (EPA 1987a) or the simple Gaussian dispersion models discussed in SEAM (EPA 1988b) can provide air concentrations around the source. Other models can be found in Volume IV of the NTGS (EPA 1989c). The Source Receptor Analysis Branch of OAQPS also can be contacted for assistance. Again, critically review all models for their applicability.

Indoor air modeling. Indoor emissions may occur as a result of transport of outdoor-generated dust or vapors indoors, or as a result of volatilization of chemicals indoors during use of contaminated water (e.g., during showering, cooking, washing). Few models are available for estimating indoor air concentrations from outside sources. For dust transport indoors, it can generally be assumed that indoor concentrations are less than those outdoors. For vapor transport indoors, concentrations indoors and outdoors can be assumed to be equivalent in most cases. However, at sites where subsurface soil gas or ground-water seepage are entering indoors, vapor concentrations inside could exceed those outdoors. Vapor concentrations resulting from indoor use of water may be greater than those outdoors, depending on the emission source characteristics, dispersion indoors, and indoor-outdoor air exchange rates. Use models discussed in the *Exposure Assessment Methods Handbook* (EPA 1989f) to evaluate volatilization of chemicals from indoor use of water.

6.5.5 ESTIMATE EXPOSURE CONCENTRATIONS IN SURFACE WATER

Data from surface water sampling and analysis may be used alone or in conjunction with fate and transport models to estimate exposure concentrations. Where the sampling points correspond to exposure points, such as at locations where fishing or recreational activities take place, or at the intake to a drinking water supply, the monitoring data can be used alone to estimate exposure concentrations. However, the data must be carefully screened. The complexity of surface water processes may lead to certain limitations in monitoring data. Among these are the following.

- **Temporal representativeness.** Surface water bodies are subject to seasonal changes in flow, temperature, and depth that may significantly affect the fate and transport of contaminants. Releases to surface water bodies often depend on storm conditions to produce surface runoff and soil erosion. Lakes are subject to seasonal stratification and changes in biological activity. Unless the surface water monitoring program has been designed to account for these phenomena, the data may not represent long-term average concentrations or short-term concentrations that may occur after storm events.

- **Spatial representativeness.** Considerable variation in concentration can occur with respect to depth and lateral location in surface water bodies. Sample locations

should be examined relative to surface water mixing zones. Concentrations within the mixing zone may be significantly higher than at downstream points where complete mixing has taken place.

- **Quantitation limit limitations.** Where large surface water bodies are involved, contaminants that enter as a result of ground-water discharge or runoff from relatively small areas may be significantly diluted. Although standard analytical methods may not be able to detect chemicals at these levels, the toxic effects of the chemicals and/or their potential to bioaccumulate may nevertheless require that such concentrations be assessed.

- **Contributions from other sources.** Surface water bodies are normally subject to contamination from many sources (e.g., pesticide runoff, stormwater, wastewater discharges, acid mine drainage). Many of the chemicals associated with these sources may be difficult to distinguish from site-related chemicals. In many cases background samples will be useful in assessing site-related contaminants from other contaminants (see Section 4.4). However, there may be other cases where a release and transport model may be required to make the distinction.

Many analytical and numerical models are available to estimate the release of contaminants to surface water and to predict the fate of contaminants once released. The models range from simple mass balance relationships to numerical codes that contain terms for chemical and biological reactions and interactions with sediments. In general, the level of information collected during the RI will tend to limit the use of the more complex models.

There are several documents that can be consulted when selecting models to estimate surface water exposure concentrations, including SEAM (EPA 1988b), the *Exposure Assessment Methods Handbook* (EPA 1989f), and *Selection Criteria for Mathematical Models Used in Exposure Assessments: Surface Water Models* (EPA 1987b). SEAM lists equations for surface water runoff and soil erosion and presents the basic mass balance relationships for estimating the effects of dilution. A list of available numerical codes for more complex modeling also is provided. The selection criteria document (EPA 1987b) provides a more in-depth discussion of numerical codes and other models. In addition, it provides guidelines and procedures for evaluating the appropriate level of complexity required for various applications. The document lists criteria to consider when selecting a surface water model, including: (1) type of water body, (2) presence of steady-state or transient conditions, (3) point versus non-point sources of contamination, (4) whether 1, 2, or 3 spatial dimensions should be considered, (5) the degree of mixing, (6) sediment interactions, and (7) chemical processes. Each of the referenced documents should be consulted prior to any surface water modeling.

6.5.6 ESTIMATE EXPOSURE CONCENTRATIONS IN SEDIMENTS

In general, use sediment monitoring data to estimate exposure concentrations. Sediment monitoring data can be expected to provide better temporal representativeness than surface water concentrations. This will especially be true in the case of contaminants such as PCBs, PAHs, and some inorganic chemicals, which are likely to remain bound to the sediments. When using monitoring data to represent exposure concentrations for direct contact exposures, data from surficial, near-shore sediments should be used.

If modeling is needed to estimate sediment exposure concentrations, consult SEAM (EPA 1988b). SEAM treats surface water and sediment together for the purpose of listing available models for the release and transport of contaminants. Models for soil erosion releases are equally applicable for estimating exposure concentrations for surface water and sediment. Many of the numerical models listed in SEAM and the surface water selection criteria document (EPA 1987b) contain sections devoted to sediment fate and transport.

6.5.7 ESTIMATE CHEMICAL CONCENTRATIONS IN FOOD

Fish and shellfish. Chemical concentrations in fish and shellfish may be measured or estimated. Site-specific measured values are preferable to estimated values, but before using such values, evaluate the sampling plan to determine if it was adequate to characterize the population and species of concern (see Section 4.5.6 for some sampling considerations). Also examine analytical procedures to determine if the quantitation limits were low enough to detect the lowest concentration potentially harmful to humans. Inadequate sampling or high levels of quantitation may lead to erroneous conclusions.

In the absence of adequate tissue measurements, first consider whether the chemical bioconcentrates (i.e., is taken up from water) or bioaccumulates (i.e., is taken up from food, sediment, and water). For example, low molecular weight volatile organic chemicals do not bioaccumulate in aquatic organisms to a great extent. Other chemicals accumulate in some species but not in others. For example, PAHs tend to accumulate in mollusk species but not in fish, which rapidly metabolize the chemicals. For those chemicals that bioconcentrate in aquatic species of concern, use the organism/water partition coefficient (i.e., bioconcentration factor, or BCF) approach to estimate steady-state concentrations. BCFs that estimate concentrations in edible tissue (muscle) are generally more appropriate for assessing human exposures from fish or shellfish ingestion than those that estimate concentrations in the whole body, although this is not true for all aquatic species or applicable to all human populations consuming fish or shellfish. When data from multiple experiments are available, select the BCF from a test that used a species most similar to the species of concern at the site, and multiply the BCF directly by the dissolved chemical concentration in water to obtain estimates of tissue concentrations. Be aware that the study from which the BCF is obtained should reflect a steady state or equilibrium condition, generally achieved over long-term exposures (although some chemicals may reach steady state rapidly in certain species). For some chemicals, BCFs may overestimate tissue levels in fish that may be exposed only for a short period of time.

When no BCF is available, estimate the BCF with a regression equation based on octanol/water partition coefficients (K_{ow}). Several equations are available in the literature. Those developed for chemicals with structural similarities to the chemical of concern should be used in preference to general equations because of better statistical correlations.

The regression equation approach to estimating BCFs can overestimate or underestimate concentrations in fish tissue depending upon the chemical of concern and the studies used to develop the regression equations. For example, high molecular weight PAHs (such as benz(a)pyrene) with high K_{ow} values lead to the prediction of high fish tissue residues. However, PAHs are rapidly metabolized in the liver, and do not appear to accumulate significantly in fish. Regression equations using K_{ow} cannot take into account such pharmacokinetics, and thus may overestimate bioconcentration. On the other hand, studies used to develop regression equations which were not representative of steady-state conditions will tend to underestimate BCFs.

Typical methods for estimating fish tissue concentrations are based on dissolved chemical concentrations in water. While chemicals present in sediment and biota may also bioaccumulate in fish, there are only limited data available to estimate contributions to fish from these sources. However, chemicals that readily adsorb to sediments, such as PCBs, can be present in surface water at concentrations below detection limits and still significantly bioaccumulate. Some models are available to assess the contribution of chemical concentrations in sediment to chemical concentrations in aquatic biota. CEAM (ERL Athens) may be of assistance in choosing and applying an appropriate model.

Plants. Site-related chemicals may be present in plants as a result of direct deposition onto plant surfaces, uptake from the soil, and uptake from the air. When possible, samples of plants or plant products should be used to estimate exposure concentrations. In the absence of monitoring data, several modeling approaches are available for estimating exposure concentrations in plants. Use of these models, however, can

introduce substantial uncertainty into an exposure assessment.

If deposition onto plants is the source of the chemical, air deposition modeling can be used in conjunction with plant interception fractions to estimate uptake. The plant interception fraction can be estimated by methods published in the literature or can be developed for a specific crop by considering crop yield and the area of the plant available for deposition.

If soil contamination is the source of the chemical, calculate the concentration in plants by multiplying soil to plant partition coefficients by soil concentrations. Use the open literature or computerized data bases to obtain these coefficients from field, microcosm, or laboratory experiments that are applicable to the type of vegetation or crop of concern (see EPA 1985c sludge documents for some). In the absence of more specific information, use general BCFs published in the literature that are not crop-specific (see Baes *et al.* 1984 for some). When using these parameters, it is important to consider that many site-specific factors affect the extent of uptake. These factors include pH, the amount of organic material present in soil, and the presence of other chemicals.

When literature values are not available, consider equations published in the literature for estimating uptake into the whole plant, into the root, and translocation from the root into above ground parts (see Calamari *et al.* 1987). Such methods require physical/chemical parameters such as K_{ow} or molecular weight and were developed using a limited data base. Scientific judgment must always be applied in the development and application of any partition coefficient, and caution must be applied in using these values in risk assessment.

Terrestrial animals. Use tissue monitoring data when available and appropriate for estimating human exposure to chemicals in the terrestrial food chain. In the absence of tissue monitoring data, use transfer coefficients together with the total chemical mass ingested by an animal per day to estimate contaminant concentrations in meat, eggs, or milk. Data to support modeling of uptake by terrestrial animals generally are not available for birds, but are available for some mammalian species. Terrestrial mammals such as cattle are simultaneously exposed to chemicals from several sources such as water, soil, corn silage, pasture grass, and hay. Cattle ingest varying amounts of these sources per day, each of which will contain a different contaminant concentration. Because all sources can be important with regard to total body burden, an approach based upon the daily mass of chemical ingested per day is recommended because it can be applied to input from many sources.

Obtain transfer coefficients from the literature (see Ng *et al.* 1977, 1979, 1982; Baes *et al.* 1984 for some), or calculate them directly from feeding studies (see Jensen *et al.* 1981; Jensen and Hummel 1982; Fries *et al.* 1973; Van Bruwaene *et al.* 1984). In the absence of this information, use regression equations in the literature for the estimation of transfer coefficients (see Travis and Arms 1988). It is important to be aware that regression equations that use feeding study results from short-term exposures may underestimate meat or milk concentrations. In addition, regression equations which rely on K_{ow} values may overestimate exposures for chemicals such as benz(a)pyrene that are rapidly metabolized. Information on the amount of feed, soil and water ingested by dairy and beef cows is available in the literature and should be combined with chemical concentrations in these media to estimate a daily dose to the animal.

6.5.8 SUMMARIZE EXPOSURE CONCENTRATIONS FOR EACH PATHWAY

Summarize the exposure concentrations derived for each pathway. Exhibit 6-10 presents a sample format.

6.6 QUANTIFICATION OF EXPOSURE: ESTIMATION OF CHEMICAL INTAKE

This section describes the methodology for calculating chemical-specific intakes for the populations and exposure pathways selected for quantitative evaluation. The general equation for estimating intake was shown in Exhibit 6-9. Remember that the intakes calculated in this step

EXHIBIT 6-10

EXAMPLE OF TABLE FORMAT FOR SUMMARIZING EXPOSURE CONCENTRATIONS

Populations/Pathways	Exposure Concentration	Comments
Current Residents		
Ingestion of ground water:		
Benzene	9 ug/L	Concentrations are the 95 percent upper confidence limit on the arithmetic average of measured concentrations in downgradient monitoring wells.
Chlordane	5.3 ug/L	
Cyanide	11 ug/L	
Direct contact with soil:		
Manganese	1200 mg/kg	Concentrations are the 95 percent upper confidence limit on the arithmetic average of measured concentrations in onsite surface soils.
Selenium	48 mg/kg	
Mercury	2 mg/kg	
Inhalation of dust:		Concentrations are based on estimates of fugitive dust generation and dispersion to nearby homes. Concentration inputs for air model are 95 percent upper confidence limit on the arithmetic average of measured concentrations in onsite soil.
Manganese	1 mg/m^3	
Selenium	0.04 mg/m^3	
Mercury	0.002 mg/m^3	

are expressed as the amount of chemical at the exchange boundary (e.g., skin, lungs, gut) and available for absorption. Intake, therefore, is not equivalent to absorbed dose, which is the amount of a chemical absorbed into the blood stream.

The sections that follow give standard equations for estimating human intakes for all possible exposure routes at a site. Values for equation variables are presented for use in evaluating residential exposures. Considerations for deriving pathway-specific variable values for populations other than residential (i.e., commercial/industrial or recreational) also are given. In general, both upper-bound (e.g., 95th percentile or maximum values) and average (mean or median) values are presented. These values can be used to calculate the RME or to evaluate uncertainty. A general discussion of which variable values should be used to calculate the RME was provided in Section 6.4.1; more specific guidance follows. A discussion of the uncertainty analysis is presented in Section 6.8.

The information presented below is organized by exposure medium and exposure route.

6.6.1 CALCULATE GROUND-WATER AND SURFACE WATER INTAKES

Individuals may be exposed to chemicals of potential concern in ground water and surface water by the following routes:

(1) ingestion of ground water or surface water used as drinking water;

(2) incidental ingestion of surface water while swimming; and

(3) dermal contact with ground water or surface water.

Inhalation exposures to chemicals that have volatilized from surface or ground water are covered in Section 6.6.3.

Intake from drinking water. Calculate residential intakes from ingestion of ground water or surface water used as drinking water, using the equation and variable values presented in Exhibit 6-11. As discussed in section 6.5.3, chemical concentration in water (CW) should be based on data from unfiltered samples. Develop pathway-specific variable values as necessary. Ingestion rates (IR) could be lower for residents who spend a portion of their day outside the home (e.g., at work). Also, exposure frequency (EF) may vary with land use. Recreational users and workers generally would be exposed less frequently than residents.

Intake from ingestion of surface water while swimming. Calculate intakes from incidental ingestion of surface water while swimming. Use the equation and variable values presented in Exhibit 6-12. Chemical concentration in water (CW) should represent unfiltered concentrations. Incidental ingestion rates (IR) while swimming have not been found in the available literature. SEAM (EPA 1988b) recommends using an incidental ingestion rate of 50 ml/hour of swimming. Exposure duration (ED) will generally be less for recreational users of a surface water compared to residents living near the surface water. Workers are not expected to be exposed via this pathway.

Intake from dermal contact. Calculate intakes from dermal contact with water while swimming, wading, etc., or during household use (e.g., bathing).

Use the equation and variable values presented in Exhibit 6-13. In this case, the calculated exposure is actually the absorbed dose, not the amount of chemical that comes in contact with the skin (i.e., intake). This is because permeability constants (PC) reflect the movement of the chemical across the skin to the stratum corneum and into the bloodstream. Be sure to record this information in the summary of exposure assessment results so that the calculated intake is compared to an appropriate toxicity reference value in the risk characterization chapter. Note that PC are based on an equilibrium partitioning and likely result in an over-estimation of absorbed dose over short exposure periods (e.g., < 1 hr). The open literature should be consulted for chemical-specific PC values. The values in SEAM (EPA 1988b) are currently being reviewed and should not be used at this time. If chemical-specific PC values are not available, the permeability of water can be used to derive a default value. (See Blank *et al.* [1984] for some values [e.g., 8.4×10^{-4} cm/hr].) Note

EXHIBIT 6-11

RESIDENTIAL EXPOSURE: INGESTION OF CHEMICALS IN DRINKING WATER [a]

(AND BEVERAGES MADE USING DRINKING WATER)

Equation:

$$\text{Intake (mg/kg-day)} = \frac{CW \times IR \times EF \times ED}{BW \times AT}$$

Where:

CW = Chemical Concentration in Water (mg/liter)
IR = Ingestion Rate (liters/day)
EF = Exposure Frequency (days/year)
ED = Exposure Duration (years)
BW = Body Weight (kg)
AT = Averaging Time (period over which exposure is averaged — days)

Variable Values:

CW: Site-specific measured or modeled value

IR: 2 liters/day (adult, 90th percentile; EPA 1989d)
1.4 liters/day (adult, average; EPA 1989d)
Age-specific values (EPA 1989d)

EF: Pathway-specific value (for residents, usually daily — 365 days/year)

ED: 70 years (lifetime; by convention)
30 years (national upper-bound time (90th percentile) at one residence; EPA 1989d)
9 years (national median time (50th percentile) at one residence; EPA 1989d)

BW: 70 kg (adult, average; EPA 1989d)
Age-specific values (EPA 1985a, 1989d)

AT: Pathway-specific period of exposure for noncarcinogenic effects (i.e., ED x 365 days/year), and 70 year lifetime for carcinogenic effects (i.e., 70 years x 365 days/year).

[a] *See Section 6.4.1 and 6.6.1 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, combine 95th or 90th percentile values for contact rate and exposure frequency and duration variables.*

EXHIBIT 6–12

RESIDENTIAL EXPOSURE: INGESTION OF CHEMICALS IN SURFACE WATER WHILE SWIMMING [a]

Equation:

$$\text{Intake (mg/kg–day)} = \frac{CW \times CR \times ET \times EF \times ED}{BW \times AT}$$

Where:

CW = Chemical Concentration in Water (mg/liter)
CR = Contact Rate (liters/hour)
ET = Exposure Time (hours/event)
EF = Exposure Frequency (events/year)
ED = Exposure Duration (years)
BW = Body Weight (kg)
AT = Averaging Time (period over which exposure is averaged — days)

Variable Values:

CW: Site–specific measured or modeled value

CR: 50 ml/hour (EPA 1989d)

ET: Pathway–specific value

EF: Pathway–specific value (should consider local climatic conditions [e. g., number of days above a given temperature] and age of potentially exposed population)
7 days/year (national average for swimming; USDOI in EPA 1988b, EPA 1989d)

ED: 70 years (lifetime; by convention)
30 years (national upper–bound time (90th percentile) at one residence; EPA 1989d)
9 years (national median time (50th percentile) at one residence; EPA 1989d)

BW: 70 kg (adult, average; EPA 1989d)
Age–specific values (EPA 1985a, 1989d)

AT: Pathway–specific period of exposure for noncarcinogenic effects (i.e., ED x 365 days/year), and 70 year lifetime for carcinogenic effects (i.e., 70 years x 365 days/year).

[a] *See Section 6.4.1 and 6.6.1 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, combine 95th or 90th percentile values for contact rate and exposure frequency and duration variables.*

EXHIBIT 6-13

RESIDENTIAL EXPOSURE: DERMAL CONTACT WITH CHEMICALS IN WATER[a]

Equation:

$$\text{Absorbed Dose (mg/kg-day)} = \frac{CW \times SA \times PC \times ET \times EF \times ED \times CF}{BW \times AT}$$

Where:

CW = Chemical Concentration in Water (mg/liter)
SA = Skin Surface Area Available for Contact (cm^2)
PC = Chemical-specific Dermal Permeability Constant (cm/hr)
ET = Exposure Time (hours/day)
EF = Exposure Frequency (days/year)
ED = Exposure Duration (years)
CF = Volumetric Conversion Factor for Water (1 liter/1000 cm^3)
BW = Body Weight (kg)
AT = Averaging Time (period over which exposure is averaged — days)

Variable Values:

CW: Site-specific measured or modeled value

SA:

50th Percentile Total Body Surface Area (m^2) (EPA 1989d, 1985a)

AGE (YRS)	MALE	FEMALE
3 < 6	0.728	0.711
6 < 9	0.931	0.919
9 < 12	1.16	1.16
12 < 15	1.49	1.48
15 < 18	1.75	1.60
Adult	1.94	1.69

50th Percentile Body Part-specific Surface Areas for Males (m^2) (EPA 1989d, 1985a)

AGE (YRS)	ARMS	HANDS	LEGS
3 < 4	0.096	0.040	0.18
6 < 7	0.11	0.041	0.24
9 < 10	0.13	0.057	0.31
Adult	0.23	0.082	0.55

[a] *See Section 6.4.1 and 6.6.1 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, combine 95th or 90th percentile values for contact rate and exposure frequency and duration variables. Use 50th percentile values for SA; see text for rationale.*

(continued)

EXHIBIT 6-13 (continued)

RESIDENTIAL EXPOSURE: DERMAL CONTACT WITH CHEMICALS IN WATER[a]

NOTE: Values for children were calculated using age-specific body surface areas and the average percentage of total body surface area represented by particular body parts in children, presented in EPA 1985a. Values for adults presented in EPA 1989d or calculated from information presented in EPA 1985a. Information on surface area of other body parts (e.g., head, feet) and for female children and adults also is presented in EPA 1985a, 1989d. Differences in body part surface areas between sexes is negligible.

PC: Consult open literature for values [Note that use of PC values results in an estimate of absorbed dose.]

ET: Pathway-specific value (consider local activity patterns if information is available)
2.6 hrs/day (national average for swimming; USDOI in EPA 1988b, EPA 1989d)

EF: Pathway-specific value (should consider local climatic conditions [e. g., number of days above a given temperature] and age of potentially exposed population)
7 days/year (national average for swimming; USDOI in EPA 1988b, EPA 1989d)

ED: 70 years (lifetime; by convention)
30 years (national upper-bound time (90th percentile) at one residence; EPA 1989d)
9 years (national median time (50th percentile) at one residence; EPA 1989d)

CF: 1 liter/1000 cm^3

BW: 70 kg (adult, average; EPA 1989d)
Age-specific values (EPA 1985a, 1989d)

AT: Pathway-specific period of exposure for noncarcinogenic effects (i.e., ED x 365 days/year), and 70 year lifetime for carcinogenic effects (i.e., 70 years x 365 days/year).

[a] *See Section 6.4.1 and 6.6.1 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, combine 95th or 90th percentile values for contact rate and exposure frequency and duration variables.*

that this approach may underestimate dermal permeability for some organic chemicals.

To calculate the reasonable maximum exposure for this pathway, 50th percentile values, instead of 95th percentile values, are used for the area of exposed skin (SA). This is because surface area and body weight are strongly correlated and 50th percentile values are most representative of the surface area of individuals of average weight (e.g., 70 kg) which is assumed for this and all other exposure pathways. Estimates of exposure for this pathway are still regarded as conservative because generally conservative assumptions are used to estimate dermal absorption (PC) and exposure frequency and duration.

Consider pathway-specific variations for the intake variables. SA will vary with activity and the extent of clothing worn. For example, a greater skin surface area would be in contact with water during bathing or swimming than when wading. Worker exposure via this pathway will depend on the type of work performed at the site, protective clothing worn, and the extent of water use and contact.

6.6.2 CALCULATE SOIL, SEDIMENT, OR DUST INTAKES

Individuals may be exposed to chemicals of potential concern in soil, sediment, or dust by the following routes:

(1) incidental ingestion; and
(2) dermal contact.

Inhalation exposures to airborne soil or dust are discussed in Section 6.6.3.

Incidental ingestion. Calculate intakes from incidental ingestion of chemicals in soil by residents using the equation and variable values presented in Exhibit 6-14. Consider population characteristics that might influence variable values. Exposure duration (ED) may be less for workers and recreational users.

The value suggested for ingestion rate (IR) for children 6 years old and younger are based primarily on fecal tracer studies and account for ingestion of indoor dust as well as outdoor soil. These values should be viewed as representative of long-term average daily ingestion rates for children and should be used in conjunction with an exposure frequency of 365 days/year. A term can be used to account for the fraction of soil or dust contacted that is presumed to be contaminated (FI). In some cases, concentrations in indoor dust can be equal to those in outdoor soil. Conceivably, in these cases, FI could be equal to 1.0.

For ingestion of chemicals in sediment, use the same equation as that used for ingestion of soil. Unless more pathway-specific values can be found in the open literature, use as default variable values the same values as those used for ingestion of soil. In most instances, contact and ingestion of sediments is not a relevant pathway for industrial/commercial land use (a notable exception to this could be workers repairing docks).

Dermal contact. Calculate exposure from dermal contact with chemicals in soil by residents using the equation and variable values presented in Exhibit 6-15. As was the case with exposure to chemicals in water, calculation of exposure for this pathway results in an estimate of the absorbed dose, not the amount of chemical in contact with the skin (i.e., intake). Absorption factors (ABS) are used to reflect the desorption of the chemical from soil and the absorption of the chemical across the skin and into the blood stream. Consult the open literature for information on chemical-specific absorption factors. In the absence of chemical-specific information, use conservative assumptions to estimate ABS.

Again, as with dermal exposure to water, 50th percentile body surface area (SA) values are used to estimate contact rates. These values are used along with average body weight because of the strong correlation between surface area and body weight. Contact rates may vary with time of year and may be greater for individuals contacting soils in the warmer months of the year when less clothing is worn (and hence, more skin is available for contact). Adherence factors (AF) are available for few soil types and body parts. The literature should be reviewed to derive AF values for other soil types and other body parts. Exposure frequency (EF) is generally determined using site-specific information and professional judgment.

EXHIBIT 6–14

RESIDENTIAL EXPOSURE:

INGESTION OF CHEMICALS IN SOIL[a]

Equation:

$$\text{Intake (mg/kg-day)} = \frac{CS \times IR \times CF \times FI \times EF \times ED}{BW \times AT}$$

Where:

CS = Chemical Concentration in Soil (mg/kg)
IR = Ingestion Rate (mg soil/day)
CF = Conversion Factor (10^{-6} kg/mg)
FI = Fraction Ingested from Contaminated Source (unitless)
EF = Exposure Frequency (days/years)
ED = Exposure Duration (years)
BW = Body Weight (kg)
AT = Averaging Time (period over which exposure is averaged — days)

Variable Values:

CS: Site-specific measured value

IR: 200 mg/day (children, 1 through 6 years old; EPA 1989g)
100 mg/day (age groups greater than 6 years old; EPA 1989g)

NOTE: IR values are default values and could change based on site-specific or other information. Research is currently ongoing to better define ingestion rates. IR values do not apply to individuals with abnormally high soil ingestion rates (i.e., pica).

CF: 10^{-6} kg/mg

FI: Pathway-specific value (should consider contaminant location and population activity patterns)

EF: 365 days/year

ED: 70 years (lifetime; by convention)
30 years (national upper-bound time (90th percentile) at one residence; EPA 1989d)
9 years (national median time (50th percentile) at one residence; EPA 1989d)

BW: 70 kg (adult, average; EPA 1989d)
16 kg (children 1 through 6 years old, 50th percentile; EPA 1985a)

AT: Pathway-specific period of exposure for noncarcinogenic effects (i.e., ED x 365 days/year), and 70 year lifetime for carcinogenic effects (i.e., 70 years x 365 days/year).

[a] *See Section 6.4.1 and 6.6.2 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, use 95th or 90th percentile values for contact rate and exposure frequency and duration variables.*

EXHIBIT 6–15

RESIDENTIAL EXPOSURE: DERMAL CONTACT WITH CHEMICALS IN SOIL[a]

Equation:

$$\text{Absorbed Dose (mg/kg-day)} = \frac{CS \times CF \times SA \times AF \times ABS \times EF \times ED}{BW \times AT}$$

Where:

CS = Chemical Concentration in Soil (mg/kg)
CF = Conversion Factor (10^{-6} kg/mg)
SA = Skin Surface Area Available for Contact (cm^2/event)
AF = Soil to Skin Adherence Factor (mg/cm^2)
ABS = Absorption Factor (unitless)
EF = Exposure Frequency (events/year)
ED = Exposure Duration (years)
BW = Body Weight (kg)
AT = Averaging Time (period over which exposure is averaged — days)

Variable Values:

CS: Based on site-specific measured value

CF: 10^{-6} kg/mg

SA:

50th Percentile Total Body Surface Area (m^2) (EPA 1989d, 1985a)

AGE (YRS)	MALE	FEMALE
3 < 6	0.728	0.711
6 < 9	0.931	0.919
9 < 12	1.16	1.16
12 < 15	1.49	1.48
15 < 18	1.75	1.60
Adult	1.94	1.69

50th Percentile Body Part-specific Surface Areas for Males (m^2) (EPA 1989d, 1985a)

AGE (YRS)	ARMS	HANDS	LEGS
3 < 4	0.096	0.040	0.18
6 < 7	0.11	0.041	0.24
9 < 10	0.13	0.057	0.31
Adult	0.23	0.082	0.55

NOTE: Values for children were calculated using age-specific body surface areas and the average percentage of total body surface area represented by particular body parts in children, presented in EPA 1985a. Values for adults presented in EPA 1989d or calculated from information presented in EPA 1985a.

[a] *See Section 6.4.1 and 6.6.2 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, combine 95th or 90th percentile values for contact rate and exposure frequency variables. Use 50th percentile values for SA; see text for rationale.*

(continued)

EXHIBIT 6–15 (continued)

RESIDENTIAL EXPOSURE: DERMAL CONTACT WITH CHEMICALS IN SOIL[a]

NOTE (continued): Information on surface area of other body parts (e.g., head, feet) and for female children and adults also is presented in EPA 1985a, 1989d. Differences in body part surface areas between sexes is negligible.

AF: 1.45 mg/cm² — commercial potting soil (for hands; EPA 1989d, EPA 1988b)
2.77 mg/cm² — kaolin clay (for hands; EPA 1989d, EPA 1988b)

ABS: Chemical-specific value (this value accounts for desorption of chemical from the soil matrix and absorption of chemical across the skin; generally, information to support a determination of ABS is limited — see text)

EF: Pathway-specific value (should consider local weather conditions [e.g.,number of rain, snow and frost-free days] and age of potentially exposed population)

ED: 70 years (lifetime; by convention)
30 years (national upper-bound time (90th percentile) at one residence; EPA 1989d)
9 years (national median time (50th percentile) at one residence; EPA 1989d)

BW: 70 kg (adult, average; EPA 1989d)
Age-specific values (EPA 1985a, 1989d)

AT: Pathway-specific period of exposure for noncarcinogenic effects (i.e., ED x 365 days/year), and 70 year lifetime for carcinogenic effects (i.e., 70 years x 365 days/year).

[a] *See Section 6.4.1 and 6.6.2 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, combine 95th or 90th percentile values for contact rate and exposure frequency and duration variables.*

"Best guess" values for children potentially useful in risk assessments are 3 times/week for fall and spring days (>32°F) and 5 times/week for summer days when children are not attending school. As discussed previously, in some cases, concentrations in indoor dust could be equal to that in outdoor environments. Therefore, at some sites, EF could be 365 days/year. Worker and recreational user contact rates are dependent on the type of activity at the site. Exposure duration (ED) and exposure frequency (EF) may be lower for workers and recreational users.

For dermal contact with sediment or dust, use the same equation as that for dermal contact with soil. As default values, also use the variable values given for dermal contact with soil unless more pathway-specific values can be found in the open literature. Adherence factors for some sediments (particularly sandy sediments) are likely to be much less than for soils because contact with water may wash the sediment off the skin. Exposure frequency for sediments also is probably lower than that for soils at many sites.

6.6.3 CALCULATE AIR INTAKES

Individuals may be exposed to chemicals of potential concern in air by inhalation of chemicals in the vapor phase or adsorbed to particulates. Dermal absorption of vapor phase chemicals is considered to be lower than inhalation intakes in many instances and generally is not considered in Superfund exposure assessments.

As with other pathways, the inhalation intakes are expressed in units of mg/kg-day. The combination of inhalation intakes with inhalation RfDs (expressed in concentration units of mg/m^3) will be discussed in Chapters 7 and 8.

Inhalation of vapor-phase chemicals. Calculate intakes from inhalation of vapor phase chemicals using the equation and variable values presented in Exhibit 6-16. Consider variations with land use. Exposure time (ET) will generally be less for workers and recreational users. For exposure times less than 24 hours per day, an hourly inhalation rate (IR) based on activity, age, and sex should be used instead of the daily IR values. Exposure duration (ED) may also be less for workers and recreational users.

Inhalation of particulate phase chemicals. Calculate intakes from inhalation of particulate phase chemicals by modifying the equations and variable values presented in Exhibit 6-16 for vapor-phase exposures. Derive inhalation estimates using the particulate concentration in air, the fraction of the particulate that is respirable (i.e., particles 10 um or less in size) and the concentration of the chemical in the respirable fraction. Note that it may be necessary to adjust intakes of particulate phase chemicals if they are to be combined with toxicity values that are based on exposure to the chemical in the vapor phase. This adjustment is done in the risk characterization step.

6.6.4 CALCULATE FOOD INTAKES

Individuals may be exposed by ingestion of chemicals of potential concern that have accumulated in food. The primary food items of concern are:

(1) fish and shellfish;

(2) vegetables and other produce; and

(3) meat, eggs, and dairy products (domestic and game species).

Ingestion of fish and shellfish. Calculate intakes from ingestion of fish and shellfish using the equation and variable values given in Exhibit 6-17. Exposure will depend in part on the availability of suitable fishing areas. The chemical concentration in fish or shellfish (CF) should be the concentration in the edible tissues (when available). The edible tissues will vary with aquatic species and with population eating habits. Residents near major commercial or recreational fisheries or shell fisheries are likely to ingest larger quantities of locally caught fish and shellfish than inland residents. In most instances, workers are not likely to be exposed via this pathway, although at some sites this may be possible.

Ingestion of vegetables or other produce. Calculate intakes from ingestion of contaminated vegetables or other produce using the equation and variable values given in Exhibit 6-18. This pathway will be most significant for farmers and for rural and urban residents consuming homegrown fruits and vegetables. For

EXHIBIT 6-16

RESIDENTIAL EXPOSURE: INHALATION OF AIRBORNE (VAPOR PHASE) CHEMICALS[a b]

Equation:

$$\text{Intake (mg/kg-day)} = \frac{CA \times IR \times ET \times EF \times ED}{BW \times AT}$$

Where:

CA = Contaminant Concentration in Air (mg/m³)
IR = Inhalation Rate (m³/hour)
ET = Exposure Time (hours/day)
EF = Exposure Frequency (days/year)
ED = Exposure Duration (years)
BW = Body Weight (kg)
AT = Averaging Time (period over which exposure is averaged — days)

Variable Values:

CA: Site-specific measured or modeled value

IR: 30 m³/day (adult, suggested upper bound value; EPA 1989d)
20 m³/day (adult, average; EPA 1989d)
Hourly rates (EPA 1989d)
Age-specific values (EPA 1985a)
Age, sex, and activity based values (EPA 1985a)
0.6 m³/hr — showering (all age groups; EPA 1989d)

ET: Pathway-specific values (dependent on duration of exposure-related activities)
12 minutes — showering (90th percentile; EPA 1989d)
7 minutes — showering (50th percentile; EPA 1989d)

EF: Pathway-specific value (dependent on frequency of showering or other exposure-related activities)

ED: 70 years (lifetime; by convention)
30 years (national upper-bound time (90th percentile) at one residence; EPA 1989d)
9 years (national median time (50th percentile) at one residence; EPA 1989d)

BW: 70 kg (adult, average; EPA 1989d)
Age-specific values (EPA 1985a, 1989d)

AT: Pathway-specific period of exposure for noncarcinogenic effects (i.e., ED x 365 days/year), and 70 year lifetime for carcinogenic effects (i.e., 70 years x 365 days/year).

[a] *See Section 6.4.1 and 6.6.3 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, use 95th or 90th percentile values for contact rate and exposure frequency and duration variables.*

[b] *The equation and variable values for vapor phase exposure can be used with modification to calculate particulate exposure. See text.*

EXHIBIT 6-17

RESIDENTIAL EXPOSURE: FOOD PATHWAY -- INGESTION OF CONTAMINATED FISH AND SHELLFISH[a]

Equation:

$$\text{Intake (mg/kg-day)} = \frac{CF \times IR \times FI \times EF \times ED}{BW \times AT}$$

Where:

CF = Contaminant Concentration in Fish (mg/kg)
IR = Ingestion Rate (kg/meal)
FI = Fraction Ingested from Contaminated Source (unitless)
EF = Exposure Frequency (meals/year)
ED = Exposure Duration (years)
BW = Body Weight (kg)
AT = Averaging Time (period over which exposure is averaged — days)

Variable Values:

CF: Site-specific measured or modeled value

IR: 0.284 kg/meal (95th percentile for fin fish; Pao *et al.* 1982)
0.113 kg/meal (50th percentile for fin fish; Pao *et al.* 1982)

132 g/day (95th percentile daily intakes averaged over three days for consumers of fin fish; Pao *et al.* 1982)
38 g/day (50th percentile daily intake, averaged over three days for consumers of fin fish; Pao *et al.* 1982)
6.5 g/day (daily intake averaged over a year; EPA 1989d.
NOTE: Daily intake values should be used in conjunction with an exposure frequency of 365 days/year.)
Specific values for age, sex, race, region and fish species are available (EPA 1989d, 1989h)

FI: Pathway-specific value (should consider local usage patterns)

EF: Pathway-specific value (should consider local population patterns if information is available)
48 days/year (average per capita for fish and shellfish; EPA Tolerance Assessment System in EPA 1989h)

ED: 70 years (lifetime; by convention)
30 years (national upper-bound time (90th percentile) at one residence; EPA 1989d)
9 years (national median time (50th percentile) at one residence; EPA 1989d)

BW: 70 kg (adult, average; EPA 1989d)
Age-specific values (EPA 1985a, 1989d)

AT: Pathway-specific period of exposure for noncarcinogenic effects (i.e., ED x 365 days/year), and 70 year lifetime for carcinogenic effects (i.e., 70 years x 365 days/year).

[a] *See Section 6.4.1 and 6.6.4 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, use 95th or 90th percentile values for intake rate and exposure frequency and duration variables.*

EXHIBIT 6-18

RESIDENTIAL EXPOSURE: FOOD PATHWAY -- INGESTION OF CONTAMINATED FRUITS AND VEGETABLES[a]

Equation:

$$\text{Intake (mg/kg-day)} = \frac{CF \times IR \times FI \times EF \times ED}{BW \times AT}$$

Where:

CF = Contaminant Concentration in Food (mg/kg)
IR = Ingestion Rate (kg/meal)
FI = Fraction Ingested from Contaminated Source (unitless)
EF = Exposure Frequency (meals/year)
ED = Exposure Duration (years)
BW = Body Weight (kg)
AT = Averaging Time (period over which exposure is averaged — days)

Variable Values:

CF: Site-specific measured value or modeled value based on soil concentration and plant:soil accumulation factor or deposition factors

IR: Specific values for a wide variety of fruits and vegetables are available (Pao *et al.* 1982)

FI: Pathway-specific value (should consider location and size of contaminated area relative to that of residential areas, as well as anticipated usage patterns)

EF: Pathway-specific value (should consider anticipated usage patterns)

ED: 70 years (lifetime; by convention)
30 years (national upper-bound time (90th percentile) at one residence: EPA 1989d)
9 years (national median time (50th percentile) at one residence: EPA 1989d)

BW: 70 kg (adult, average; EPA 1989d)
Age-specific values (EPA 1985a, 1989d)

AT: Pathway-specific period of exposure for noncarcinogenic effects (i.e., ED x 365 days/year), and 70 year lifetime for carcinogenic effects (i.e., 70 years x 365 days/year).

[a] *See Section 6.4.1 and 6.6.4 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, use 95th or 90th percentile values for contact rate and exposure frequency and duration variables.*

contaminated backyard gardens, the fraction of food ingested that is contaminated (FI) can be estimated using information on the fraction of fruits or vegetables consumed daily that is home grown (HF). EPA (1989d) provides HF values for fruit (0.20, average; 0.30 worst-case) and vegetables (0.25, average; 0.40, worst-case). (Worst-case values can be used as estimates of the 95th percentile value.) Pao *et al.* (1982) provides specific values for a variety of fruits and vegetables.

Workers are not likely to be exposed via this pathway. Recreational users could be exposed from consuming wild fruits or vegetables from the site, although such exposures are likely to be negligible.

Ingestion of meat, eggs, and dairy products. Calculate intakes from ingestion of contaminated meat and dairy products using the equation and variable values given in Exhibit 6-19. Derive pathway-specific values as necessary. Rural residents may consume poultry as well as livestock and wild game that have been exposed to contaminants at the site. The fraction of food ingested daily that is contaminated (FI) can be estimated for beef and dairy products using information provided in EPA (1989d) on the fraction of these foods that is homegrown (HF). HF for beef is estimated to be 0.44 (average) and 0.75 (worst-case). HF for dairy products is estimated to be 0.40 (average) and 0.75 (worst-case). (Worst-case values can be used as estimates of the 95th percentile value.) Consider land-use variations. Workers are not likely to be exposed via this pathway. Exposure duration (ED) and exposure frequency (EF) will likely be less for recreational users (e.g., hunters).

6.7 COMBINING CHEMICAL INTAKES ACROSS PATHWAYS

As discussed previously, the RME at a site reflects the RME for a pathway as well as the RME across pathways. A given population may be exposed to a chemical from several exposure routes. For example, residents may be exposed to chemicals in ground water via ingestion of drinking water and via inhalation of chemicals that have volatilized from ground water during its use. They also could be exposed to chemicals in vapors or dust that have migrated from the site. To calculate an exposure that is a reasonable maximum across pathways, it may be necessary to combine the RME for one pathway with an estimate of more typical exposure for another pathway (see Section 8.3.1). The average variable values identified in the previous sections can be used to calculate intakes for these more typical exposures. At this point in the assessment, estimated intakes are not summed across pathways; this is addressed in the risk characterization chapter. However, the assessor should organize the results of the previous exposure analyses (including any estimates of typical exposure) by grouping all applicable exposure pathway for each exposed population. This organization will allow risks from appropriate exposures to be combined in the risk characterization chapter (see Exhibit 6-22 for a sample summary format).

6.8 EVALUATING UNCERTAINTY

The discussion of uncertainty is a very important component of the exposure assessment. Based on the sources and degree of uncertainty associated with estimates of exposure, the decision-maker will evaluate whether the exposure estimates are the maximum exposures that can be reasonably expected to occur. Section 8.4 provides a discussion of how the exposure uncertainty analysis is incorporated into the uncertainty analysis for the entire risk assessment.

The discussion of uncertainty in the exposure assessment chapter should be separated into two parts. The first part is a tabular summary of the values used to estimate exposure and the range of these values. The table should include the variables that appear in the exposure equation as well as those used to estimate exposure concentrations (e.g., model variables). A simple example of this table is shown in Exhibit 6-20. For each variable, the table should include the range of possible values, the midpoint of the range (useful values for this part are given in Exhibits 6-11 through 6-19), and the value used to estimate exposure. In addition, a brief description

EXHIBIT 6-19

RESIDENTIAL EXPOSURE: FOOD PATHWAY -- INGESTION OF CONTAMINATED MEAT, EGGS, AND DAIRY PRODUCTS [a]

Equation:

$$\text{Intake (mg/kg-day)} = \frac{CF \times IR \times FI \times EF \times ED}{BW \times AT}$$

Where:

CF = Contaminant Concentration in Food (mg/kg)
IR = Ingestion Rate (kg/meal)
FI = Fraction Ingested from Contaminated Source (unitless)
EF = Exposure Frequency (meals/year)
ED = Exposure Duration (years)
BW = Body Weight (kg)
AT = Averaging Time (period over which exposure is averaged — days)

Variable Values:

CF: Site-specific measured or modeled value. Based on soil concentrations, plant (feed) accumulation factors, and feed-to-meat or feed-to-dairy product transfer coefficients

IR: 0.28 kg/meal — beef (95th percentile; Pao *et al.* 1982)
0.112 kg/meal — beef (50th percentile; Pao *et al.* 1982)
Specific values for other meats are available (Pao *et al.* 1982)

0.150 kg/meal — eggs (95th percentile; Pao *et al.* 1982)
0.064 kg/meal — eggs (50th percentile; Pao *et al.* 1982)

Specific values for milk, cheese and other dairy products are available (Pao *et al.* 1982)

FI: Pathway-specific value (should consider location and size of contaminated area relative to that of residential areas, as well as anticipated usage patterns)

EF: Pathway-specific value (should consider anticipated usage patterns)

ED: 70 years (lifetime; by convention)
30 years (national upper-bound time (90th percentile) at one residence; EPA 1989d)
9 years (national median time (50th percentile) at one residence; EPA1989d)

BW: 70 kg (adult, average; EPA 1989d)
Age-specific values (EPA 1985a, 1989d)

AT: Pathway-specific period of exposure for noncarcinogenic effects (i.e., ED x 365 days/year), and 70 year lifetime for carcinogenic effects (i.e., 70 years x 365 days/year).

[a] *See Section 6.4.1 and 6.6.4 for a discussion of which variable values should be used to calculate the reasonable maximum exposure. In general, use 95th or 90th percentile values for contact rate and exposure frequency and duration.*

EXHIBIT 6–20

EXAMPLE OF TABLE FORMAT FOR SUMMARIZING VALUES USED TO ESTIMATE EXPOSURE

Variable	Range	Midpoint	Value Used	Brief Rationale
PCB concentration in soil (mg/kg)	ND – 3,500	250 (arithmetic mean)		
Chronic exposure (mg/kg)			1,400	95th percentile upperbound estimate of mean concentration
Acute exposure (mg/kg)			3,500	Maximum detected concentration
Adult soil ingestion rate (mg/d)	0 – 170	17 (arithmetic mean)	100	Range based on assumptions regarding soil adherence and percent ingestion. Value used is from EPA 1989g.
Exposure frequency (days/wk)	1 – 7	3	5	Best professional judgment.
Exposure duration (years)	1 – 20	10	20	Best professional judgment.

of the selection rationale should be included. The discussion that accompanies the table in the exposure assessment chapter should identify which variables have the greatest range and provide additional justification for the use of values that may be less certain.

The second part of the uncertainty discussion is to summarize the major assumptions of the exposure assessment, to discuss the uncertainty associated with each, and to describe how this uncertainty is expected to affect the estimate of exposure. Sources of uncertainty that should be addressed include 1) the monitoring data, which may or may not be representative of actual conditions at the site; 2) the exposure models, assumptions and input variables used to estimate exposure concentrations; and 3) the values of the intake variables used to calculate intakes. Each of these sources should be discussed in the summary section of the exposure assessment. A table may be useful in summarizing this information. Exhibit 6-21 presents a sample format.

A supplemental approach to uncertainty analysis is to use analytical methods (e.g., first-order uncertainty analysis) or numerical methods (e.g., Monte Carlo analysis). These methods and their limitations are described in greater detail in Section 8.4 It is recommended that these analyses be used only after approval of the EPA project manager, and then, only as a part of the uncertainty analysis (and not as a basis for the reasonable maximum exposure).

6.9 SUMMARIZING AND PRESENTING THE EXPOSURE ASSESSMENT RESULTS

At this point, the exposure assessor should summarize the results of the exposure assessment. The summary information should be presented in table format and should list the estimated chemical-specific intakes for each pathway. The pathways should be grouped by population so that risks can be combined across pathways as appropriate. The summary information should be further grouped by current and future use categories. Within these categories, subchronic and chronic daily intakes should be summarized separately. Exhibit 6-22 presents a sample format for this summary information. In addition to the summary table, provide sample calculations for each pathway, to aid in the review of the calculations.

EXHIBIT 6-21

EXAMPLE OF AN UNCERTAINTY TABLE FOR EXPOSURE ASSESSMENT

ASSUMPTION	EFFECT ON EXPOSURE [a]		
	Potential Magnitude for Over-Estimation of Exposure	Potential Magnitude for Under-Estimation of Exposure	Potential Magnitude for Over- or Under Estimation of Exposure
Environmental Sampling and Analysis			
Sufficient samples may not have been taken to characterize the media being evaluated, especially with respect to currently available soil data.			Moderate
Systematic or random errors in the chemical analyses may yield erroneous data.			Low
Fate and Transport Modeling			
Chemicals in fish will be at equilibrium with chemical concentrations in water.	Low		
Use of a Gaussian dispersion model to estimate air concentrations offsite.			Low
Use of a box model to estimate air concentrations onsite.	Low		
Use of Cowherd's model to estimate vehicle emission factors.		Moderate	
Exposure Parameter Estimation			
The standard assumptions regarding body weight, period exposed, life expectancy, population characteristics, and lifestyle may not be representative of any actual exposure situation.			Moderate
The amount of media intake is assumed to be constant and representative of the exposed population.	Moderate		
Assumption of daily lifetime exposure for residents.	Moderate to High		
Use of "hot spot" soil data for upper-bound lifetime exposure	Moderate to High		

[a] *As a general guideline, assumptions marked as "low", may affect estimates of exposure by less than one order of magnitude; assumptions marked "moderate" may affect estimates of exposure by between one and two orders of magnitude; and assumptions marked "high" may affect estimates of exposure by more than two orders of magnitude.*

EXHIBIT 6-22

EXAMPLE OF TABLE FORMAT FOR SUMMARIZING THE RESULTS OF THE EXPOSURE ASSESSMENT— CURRENT LAND USE [a]

Population	Exposure Pathway	Chemical	Chronic Daily Intake (CDI) (mg/kg-day)	
			Carcinogenic Effects	Noncarcinogenic Effects
Residents	Ingestion of ground water that has migrated from the site to downgradient local wells	Benzene	0.00025	— [b]
		Chlordane	0.00015	0.00035
		Phenol	— [c]	0.1
		Cyanide	— [c]	0.0003
		Nitrobenzene	— [c]	0.0001
	Inhalation of chemicals that have volatilized from ground water during use	Benzene	0.000013	— [b]
	Ingestion of fish that have accumulated chemicals in nearby lake	Chlordane	0.00008	0.00019
		MEK	— [c]	0.005
		Phenol	— [c]	0.08

[a] *Similar tables should be prepared for all subchronic daily intake (SDI) estimates as well as for all CDI and SDI estimates under future land use conditions.*

[b] *CDI for noncarcinogenic effects not calculated for benzene because it does not have an EPA-verified chronic reference dose (as of the publication date of this manual).*

[c] *CDI for carcinogenic effects not calculated for chemicals not considered by EPA to be potential human carcinogens (as of the publication date of this manual).*

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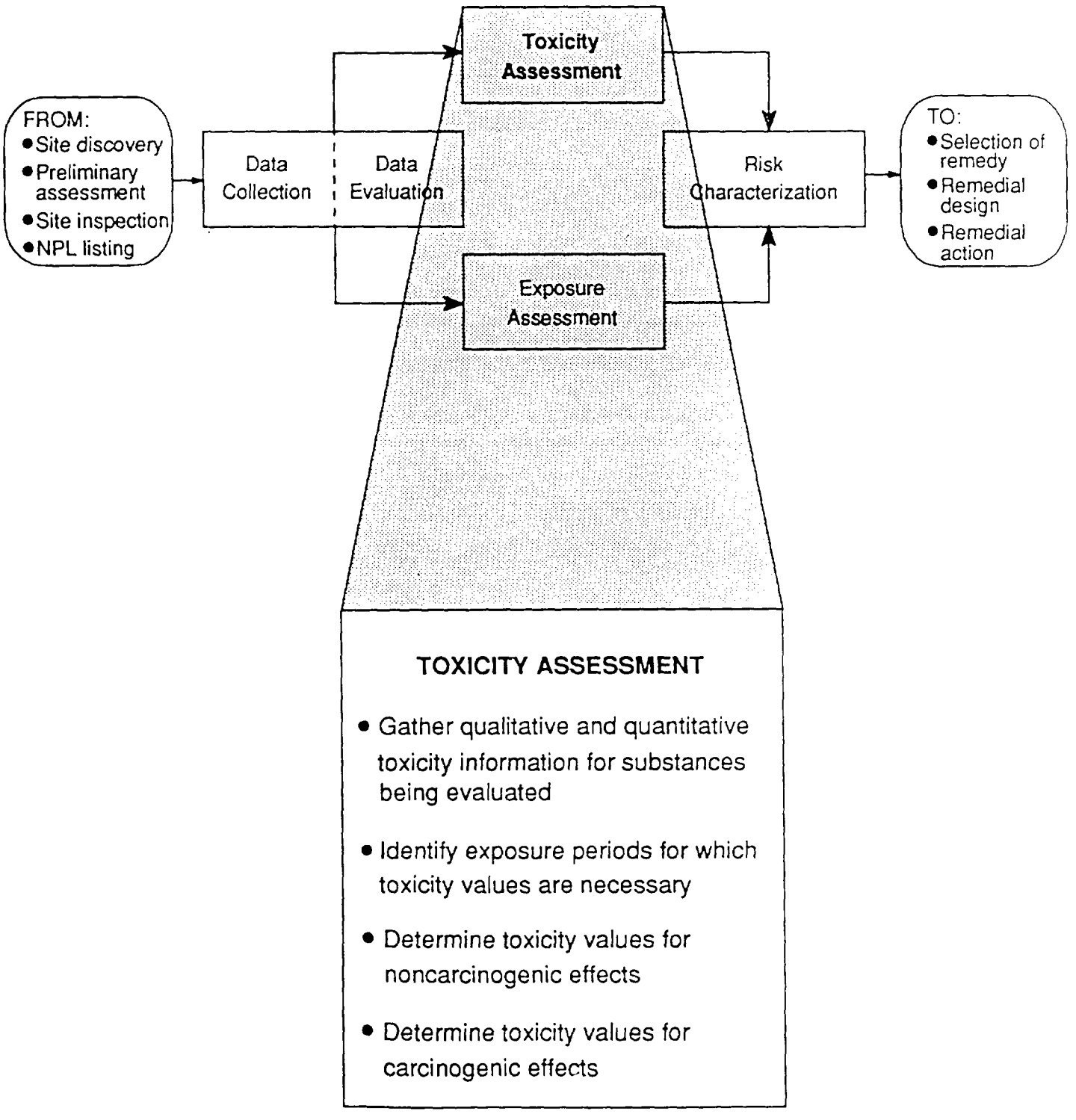
CHAPTER 7

TOXICITY ASSESSMENT



CHAPTER 7

TOXICITY ASSESSMENT

The purpose of the toxicity assessment is to weigh available evidence regarding the potential for particular contaminants to cause adverse effects in exposed individuals and to provide, where possible, an estimate of the relationship between the extent of exposure to a contaminant and the increased likelihood and/or severity of adverse effects.

Toxicity assessment for contaminants found at Superfund sites is generally accomplished in two steps: hazard identification and dose-response assessment. These two steps were first discussed in the National Academy of Sciences' publication entitled *Risk Assessment in the Federal Government - Managing the Process* and more recently in EPA's *Guidelines for Carcinogen Risk Assessment* (NAS 1983, EPA 1986). The first step, hazard identification, is the process of determining whether exposure to an agent can cause an increase in the incidence of a particular adverse health effect (e.g., cancer, birth defect) and whether the adverse health effect is likely to occur in humans. Hazard identification involves characterizing the nature and strength of the evidence of causation. The second step, dose-response evaluation, is the process of quantitatively evaluating the toxicity information and characterizing the relationship between the dose of the contaminant administered or received and the incidence of adverse health effects in the exposed population. From this quantitative dose-response relationship, toxicity values (e.g., reference doses and slope factors) are derived that can be used to estimate the incidence or potential for adverse effects as a function of human exposure to the agent. These toxicity values are used in the risk characterization step to estimate the likelihood of adverse effects occurring in humans at different exposure levels.

Toxicity assessment is an integral part of the overall Superfund site risk assessment. Although toxicity information is critical to the risk assessment, the amount of new toxicological evaluation of primary data required to complete this step is limited in most cases. EPA has performed the toxicity assessment step for numerous chemicals and has made available the resulting toxicity information and toxicity values, which have undergone extensive peer review. At some sites, however, there will be significant data analysis and interpretation issues that should be addressed by an experienced toxicologist. This chapter provides step-by-step guidance for locating EPA toxicity assessments and accompanying values, and advises how to determine which values are most appropriate when multiple values exist. Prior to this procedural discussion, background

ACRONYMS FOR CHAPTER 7

ADI =	Acceptable Daily Intake
AIC =	Acceptable Intake for Chronic Exposure
AIS =	Acceptable Intake for Subchronic Exposure
CRAVE =	Carcinogen Risk Assessment Verification Endeavor
ECAO =	Environmental Criteria and Assessment Office
HAD =	Health Assessment Document
HEA =	Health Effects Assessment
HEAST =	Health Effects Assessment Summary Tables
HEED =	Health and Environmental Effects Document
HEEP =	Health and Environmental Effects Profile
IRIS =	Integrated Risk Information System
LOAEL =	Lowest-Observed-Adverse-Effect-Level
NOAEL =	No-Observed-Adverse-Effect-Level
NOEL =	No-Observed-Effect-Level
RfD =	Reference Dose (when used without other modifiers, RfD generally refers to chronic reference dose)
RfD_{dt} =	Developmental Reference Dose
RfD_s =	Subchronic Reference Dose

DEFINITIONS FOR CHAPTER 7

Acceptable Daily Intake (ADI). An estimate similar in concept to the RfD, but derived using a less strictly defined methodology. RfDs have replaced ADIs as the Agency's preferred values for use in evaluating potential noncarcinogenic health effects resulting from exposure to a chemical.

Acceptable Intake for Chronic Exposure (AIC). An estimate similar in concept to the RfD, but derived using a less strictly defined methodology. Chronic RfDs have replaced AICs as the Agency's preferred values for use in evaluating potential noncarcinogenic health effects resulting from chronic exposure to a chemical.

Acceptable Intake for Subchronic Exposure (AIS). An estimate similar in concept to the subchronic RfD, but derived using a less strictly defined methodology. Subchronic RfDs have replaced AISs as the Agency's preferred values for use in evaluating potential noncarcinogenic health effects resulting from subchronic exposure to a chemical.

Chronic Reference Dose (RfD). An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime. Chronic RfDs are specifically developed to be protective for long-term exposure to a compound (as a Superfund program guideline, seven years to lifetime).

Developmental Reference Dose (RfD_{dt}). An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of an exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of developmental effects. Developmental RfDs are used to evaluate the effects of a single exposure event.

Dose-response Evaluation. The process of quantitatively evaluating toxicity information and characterizing the relationship between the dose of a contaminant administered or received and the incidence of adverse health effects in the exposed population. From the quantitative dose-response relationship, toxicity values are derived that are used in the risk characterization step to estimate the likelihood of adverse effects occurring in humans at different exposure levels.

Hazard Identification. The process of determining whether exposure to an agent can cause an increase in the incidence of a particular adverse health effect (e.g., cancer, birth defect) and whether the adverse health effect is likely to occur in humans.

Integrated Risk Information System (IRIS). An EPA data base containing verified RfDs and slope factors and up-to-date health risk and EPA regulatory information for numerous chemicals. IRIS is EPA's preferred source for toxicity information for Superfund.

Lowest-Observed-Adverse-Effect-Level (LOAEL). In dose-response experiments, the lowest exposure level at which there are statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control group.

No-Observed-Adverse-Effect-Level (NOAEL). In dose-response experiments, an exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered to be adverse, nor precursors to specific adverse effects. In an experiment with more than one NOAEL, the regulatory focus is primarily on the highest one, leading to the common usage of the term NOAEL to mean the highest exposure level without adverse effect.

No-Observed-Effect-Level (NOEL). In dose-response experiments, an exposure level at which there are no statistically or biologically significant increases in the frequency or severity of any effect between the exposed population and its appropriate control.

Reference Dose (RfD). The Agency's preferred toxicity value for evaluating noncarcinogenic effects resulting from exposures at Superfund sites. See specific entries for chronic RfD, subchronic RfD, and developmental RfD. The acronym RfD, when used without other modifiers, either refers generically to all types of RfDs or specifically to chronic RfDs; it never refers specifically to subchronic or developmental RfDs.

(continued)

DEFINITIONS FOR CHAPTER 7
(continued)

Slope Factor. A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.

Subchronic Reference Dose (RfD_s). An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a portion of a lifetime (as a Superfund program guideline, two weeks to seven years).

Toxicity Value. A numerical expression of a substance's dose-response relationship that is used in risk assessments. The most common toxicity values used in Superfund program risk assessments are reference doses (for noncarcinogenic effects) and slope factors (for carcinogenic effects).

Weight-of-Evidence Classification. An EPA classification system for characterizing the extent to which the available data indicate that an agent is a human carcinogen. Recently, EPA has developed weight-of-evidence classification systems for some other kinds of toxic effects, such as developmental effects.

information regarding EPA's methods for toxicity assessment is provided to assist the risk assessor in understanding the basis of the toxicity values and the limitations of their use. The steps of the toxicity assessment are illustrated in Exhibit 7-1.

Derivation and interpretation of toxicity values requires toxicological expertise and should not be undertaken by those without training and experience. Detailed guidance for deriving toxicity values is beyond the scope of this document. For those persons interested in obtaining additional information about EPA's methods for toxicity assessment, references to appropriate guidance documents are given throughout this chapter.

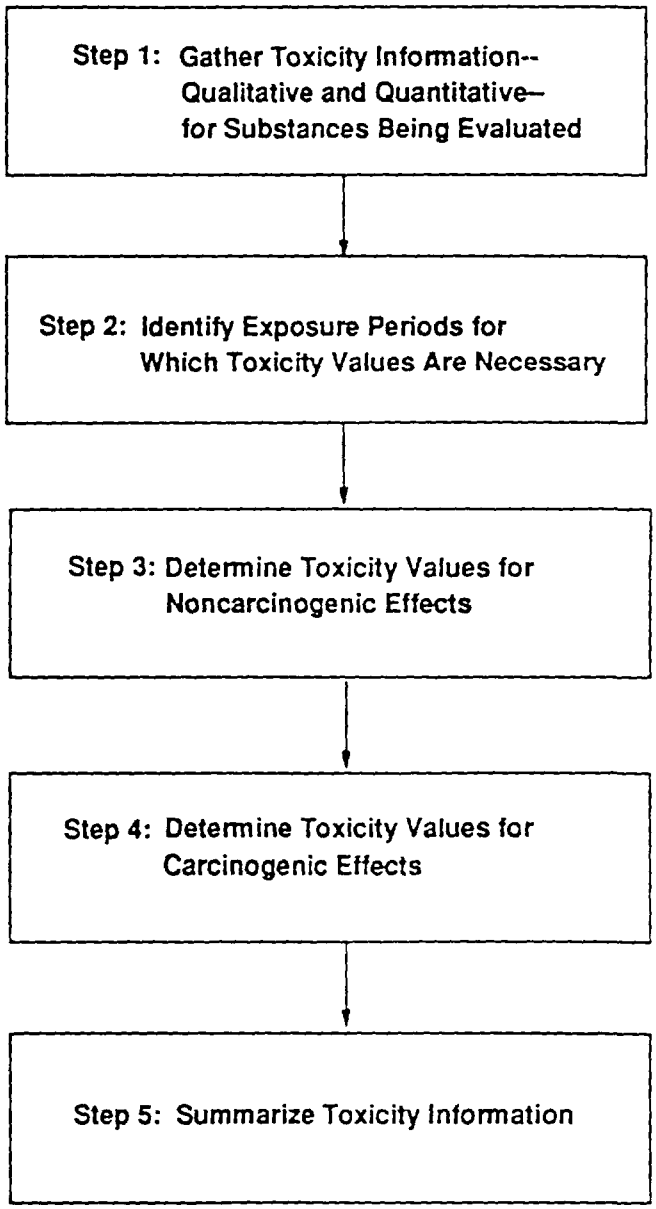
7.1 TYPES OF TOXICOLOGICAL INFORMATION CONSIDERED IN TOXICITY ASSESSMENT

This section summarizes information from several EPA documents (especially EPA 1989a, f) on the basic types of data used in toxicity assessment. As part of the hazard identification step of the toxicity assessment, EPA gathers evidence from a variety of sources regarding the potential for a substance to cause adverse health effects (carcinogenic and noncarcinogenic) in humans. These sources may include controlled epidemiologic investigations, clinical studies, and experimental animal studies. Supporting information may be obtained from sources such as *in vitro* test results and comparisons of structure-activity relationships.

7.1.1 HUMAN DATA

Well-conducted epidemiologic studies that show a positive association between an agent and a disease are accepted as the most convincing evidence about human risk. At present, however, human data adequate to serve as the sole basis of a dose-response assessment are available for only a few chemicals. Humans are generally exposed in the workplace or by accident, and because these types of exposures are not intentional, the circumstances of the exposures (concentration and time) may not be well known. Often the incidence of effects is low, the number of exposed individuals is small, the latent period between exposure and disease is long, and exposures are to mixed and multiple substances. Exposed populations may be heterogeneous, varying in age, sex, genetic constitution, diet, occupational and home environment, activity patterns, and other cultural factors affecting susceptibility. For these reasons, epidemiologic data require careful interpretation. If adequate human studies (confirmed for validity and applicability) exist, these studies are given first priority in the dose-response assessment, and animal toxicity studies are used as supportive evidence.

EXHIBIT 7-1
STEPS IN TOXICITY ASSESSMENT



Human studies having inadequate exposure-response information for a quantitative assessment are often used as supporting data. Such studies may establish a qualitative relationship between environmental exposures and the presence of an adverse effect in exposed human populations. For example, case reports of exposures resulting in effects similar to the types of effects observed in animals provide support for the conclusions drawn from the animal data.

7.1.2 ANIMAL DATA

The toxicity data base for most chemicals lacks sufficient information on toxic effects in humans. In such cases, EPA may infer the potential for the substance to cause an adverse effect in humans from toxicity information drawn from experiments conducted on non-human mammals, such as the rat, mouse, rabbit, guinea pig, hamster, dog, or monkey. The inference that humans and animals (mammals) are similar, on average, in intrinsic susceptibility to toxic chemicals and that data from animals can in many cases be used as a surrogate for data from humans is the basic premise of modern toxicology. This concept is particularly important in the regulation of toxic chemicals. There are occasions, however, in which observations in animals may be of uncertain relevance to humans. EPA considers the likelihood that the agent will have adverse effects in humans to increase as similar results are observed across sexes, strains, species, and routes of exposure in animal studies.

7.1.3 SUPPORTING DATA

Several other types of studies used to support conclusions about the likelihood of occurrence of adverse health effects in humans are described below. At the present time, EPA considers all of these types of data to be supportive, not definitive, in assessing the potential for adverse health effects in humans.

Metabolic and other pharmacokinetic studies may be used to provide insights into the mechanism of action of a particular compound. By comparing the metabolism of a compound exhibiting a toxic effect in an animal with the corresponding metabolism in humans, evidence for the potential of the compound to have toxic effects in humans may be obtained.

Studies using cell cultures or microorganisms may be used to provide insights into a compound's potential for biological activity. For example, tests for point mutations, numerical and structural chromosome aberrations, DNA damage/repair, and cell transformation may provide supportive evidence of carcinogenicity and may give information on potential mechanisms of carcinogenicity. It should be noted, however, that lack of positive results in short-term tests for genotoxicity is not considered a basis for discounting positive results in long-term carcinogenicity studies in animals.

Structure-activity studies (i.e., predictions of toxicologic activity based on analysis of chemical structure) are another potential source of supporting data. Under certain circumstances, the known activity of one compound may be used to estimate the activity of another structurally related compound for which specific data are lacking.

7.2 TOXICITY ASSESSMENT FOR NONCARCINOGENIC EFFECTS

This section summarizes how the types of toxicity information presented in Section 7.1 are considered in the toxicity assessment for noncarcinogenic effects. A reference dose, or RfD, is the toxicity value used most often in evaluating noncarcinogenic effects resulting from exposures at Superfund sites. Additionally, One-day or Ten-day Health Advisories (HAs) may be used to evaluate short-term oral exposures. The methods EPA uses for developing RfDs and HAs are described below. Various types of RfDs are available depending on the exposure route (oral or inhalation), the critical effect (developmental or other), and the length of exposure being evaluated (chronic, subchronic, or single event). This section is intended to be a summary description only; for additional details, refer to the appropriate guidelines and other sources listed as references for this chapter (especially EPA 1986b, EPA 1989b-f).

A chronic RfD is defined as an estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an

appreciable risk of deleterious effects during a lifetime. Chronic RfDs are specifically developed to be protective for long-term exposure to a compound. As a guideline for Superfund program risk assessments, chronic RfDs generally should be used to evaluate the potential noncarcinogenic effects associated with exposure periods between 7 years (approximately 10 percent of a human lifetime) and a lifetime. Many chronic RfDs have been reviewed and verified by an intra-Agency RfD Workgroup and entered into the Agency's Integrated Risk Information System (IRIS).

FORMER TERMINOLOGY

Prior to the development of RfDs, noncarcinogenic effects of chronic exposures were evaluated using values called acceptable daily intakes (ADIs) or acceptable intakes for chronic exposure (AICs). While ADIs and AICs are similar in concept to RfDs, RfDs have been derived using a more strictly defined methodology and represent the Agency's preferred toxicity values. Furthermore, many chronic RfDs have been reviewed and verified by an intra-Agency RfD Workgroup; these verified RfDs represent an Agency consensus and are preferred over other RfDs that have not undergone such review (see Section 7.2.7, Verification of RfDs). Similarly, acceptable intakes for subchronic exposures (AISs) have been superseded by the more strictly defined subchronic RfD values. Therefore, the former terminology (ADI, AIC, AIS) should no longer be used in Superfund program risk assessments.

More recently, EPA has begun developing subchronic RfDs (RfD_s), which are useful for characterizing potential noncarcinogenic effects associated with shorter-term exposures, and developmental RfDs (RfD_ds), which are useful specifically for assessing potential developmental effects resulting from exposure to a compound. As a guideline for Superfund program risk assessments, subchronic RfDs should be used to evaluate the potential noncarcinogenic effects of exposure periods between two weeks and seven years. Such short-term exposures can result when a particular activity is performed for a limited number of years or when a chemical with a short half-life degrades to negligible concentrations within several months. Developmental RfDs are used to evaluate the potential effects on a developing organism following a single exposure event.

7.2.1 CONCEPT OF THRESHOLD

For many noncarcinogenic effects, protective mechanisms are believed to exist that must be overcome before an adverse effect is manifested. For example, where a large number of cells perform the same or similar function, the cell population may have to be significantly depleted before an effect is seen. As a result, a range of exposures exists from zero to some finite value that can be tolerated by the organism with essentially no chance of expression of adverse effects. In developing a toxicity value for evaluating noncarcinogenic effects (i.e., an RfD), the approach is to identify the upper bound of this tolerance range (i.e., the maximum subthreshold level). Because variability exists in the human population, attempts are made to identify a subthreshold level protective of sensitive individuals in the population. For most chemicals, this level can only be estimated; the RfD incorporates uncertainty factors indicating the degree or extrapolation used to derive the estimated value. RfD summaries in IRIS also contain a statement expressing the overall confidence that the evaluators have in the RfD (high, medium, or low). The RfD is generally considered to have uncertainty spanning an order of magnitude or more, and therefore the RfD should not be viewed as a strict scientific demarcation between what level is toxic and nontoxic.

7.2.2 DERIVATION OF AN ORAL RfD (RfD_o)

Identifying the critical study and determining the NOAEL. In the development of oral RfDs, all available studies examining the toxicity of a chemical following exposure by the oral route are gathered and judged for scientific merit. Occasionally, studies based on other exposure routes (e.g., inhalation) are considered, and the data are adjusted for application to the oral route. Any differences between studies are reconciled and an overall evaluation is reached. If adequate human data are available, this information is used as the basis of the RfD. Otherwise, animal study data are used; in these cases, a series of professional judgments are made that involve, among other considerations, an assessment of the relevance and scientific quality of the experimental studies. If data from several animal studies are being evaluated, EPA first seeks to identify the

animal model that is most relevant to humans based on a defensible biological rationale, for instance, using comparative metabolic and pharmacokinetic data. In the absence of a species that is clearly the most relevant, EPA assumes that humans are at least as sensitive to the substance as the most sensitive animal species tested. Therefore, as a matter of science policy, the study on the most sensitive species (the species showing a toxic effect at the lowest administered dose) is selected as the critical study for the basis of the RfD. The effect characterized by the "lowest-observed-adverse-effect-level" (LOAEL) after dosimetric conversions to adjust for species differences is referred to as the critical toxic effect.

After the critical study and toxic effect have been selected, EPA identifies the experimental exposure level representing the highest level tested at which no adverse effects (including the critical toxic effect) were demonstrated. This highest "no-observed-adverse-effect level" (NOAEL) is the key datum obtained from the study of the dose-response relationship. A NOAEL observed in an animal study in which the exposure was intermittent (such as five days per week) is adjusted to reflect continuous exposure.

The NOAEL is selected based in part on the assumption that if the critical toxic effect is prevented, then all toxic effects are prevented. The NOAEL for the critical toxic effect should not be confused with the "no-observed-effect level" (NOEL). The NOEL corresponds to the exposure level at which no effect at all has been observed; frequently, effects are observed that are not considered to be of toxicological significance. In some studies, only a LOAEL rather than a NOAEL is available. The use of a LOAEL, however, requires the use of an additional uncertainty factor (see below).

MULTIPLE TOXIC EFFECTS AND RfDs

The RfD is developed from a NOAEL for the most sensitive, or critical, toxic effect based in part on the assumption that if the critical toxic effect is prevented, then all toxic effects are prevented. It should be remembered during the risk characterization step of the risk assessment that if exposure levels exceed the RfD, then adverse effects in addition to the critical toxic effect may begin to appear.

Applying uncertainty factors. The RfD is derived from the NOAEL (or LOAEL) for the critical toxic effect by consistent application of uncertainty factors (UFs) and a modifying factor (MF). The uncertainty factors generally consist of multiples of 10 (although values less than 10 are sometimes used), with each factor representing a specific area of uncertainty inherent in the extrapolation from the available data. The bases for application of different uncertainty factors are explained below.

- A UF of 10 is used to account for variation in the general population and is intended to protect sensitive subpopulations (e.g., elderly, children).
- A UF of 10 is used when extrapolating from animals to humans. This factor is intended to account for the interspecies variability between humans and other mammals.
- A UF of 10 is used when a NOAEL derived from a subchronic instead of a chronic study is used as the basis for a chronic RfD.
- A UF of 10 is used when a LOAEL is used instead of a NOAEL. This factor is intended to account for the uncertainty associated with extrapolating from LOAELs to NOAELs.

In addition to the UFs listed above, a modifying factor (MF) is applied.

- An MF ranging from >0 to 10 is included to reflect a qualitative professional assessment of additional uncertainties in the critical study and in the entire data base for the chemical not explicitly addressed by the preceding uncertainty factors. The default value for the MF is 1.[1]

To calculate the RfD, the appropriate NOAEL (or the LOAEL if a suitable NOAEL is not available) is divided by the product of all of the

applicable uncertainty factors and the modifying factor. That is:

$$RfD = NOAEL \text{ or } LOAEL/(UF_1 \times UF_2 \ldots \times MF)$$

Oral RfDs typically are expressed as one significant figure in units of mg/kg-day. These concepts are shown graphically in EPA (1989g). To date, most RfDs developed by EPA and included in the sources listed in Section 7.4 are based on administered doses, not absorbed doses (see box on page 7-10).

7.2.3 DERIVATION OF AN INHALATION RfD (RfD_i)

The methods EPA uses in the derivation of inhalation RfDs are similar in concept to those used for oral RfDs; however, the actual analysis of inhalation exposures is more complex than oral exposures due to (1) the dynamics of the respiratory system and its diversity across species and (2) differences in the physicochemical properties of contaminants. Additional information can be found in EPA's *Interim Methods for Development of Inhalation Reference Doses* (EPA 1989d).

Identifying the critical study and determining the NOAEL. Although in theory the identification of the critical study and the determination of the NOAEL is similar for oral and inhalation exposures, several important differences should be noted. In selecting the most appropriate study, EPA considers differences in respiratory anatomy and physiology, as well as differences in the physicochemical characteristics of the contaminant. Differences in respiratory anatomy and physiology may affect the pattern of contaminant deposition in the respiratory tract, and the clearance and redistribution of the agent. Consequently, the different species may not receive the same dose of the contaminant at the same locations within the respiratory tract even though both species were exposed to the same particle or gas concentration. Differences in the physicochemical characteristics of the contaminants, such as the size and shape of a particle or whether the contaminant is an aerosol or a gas, also influence deposition, clearance, and redistribution.

In inhalation exposures, the target tissue may be a portion of the respiratory tract or, if the contaminant can be absorbed and distributed through the body, some extrarespiratory organ. Because the pattern of deposition may influence concentrations at the alveolar exchange boundary or different tissues of the lung, the toxic health effect observed may be more directly related to the pattern of deposition than to the exposure concentration. Consequently, EPA considers the deposition, clearance mechanisms, and the physicochemical properties of the inhaled agent in determining the effective dose delivered to the target organ.

Doses calculated in animals are converted to equivalent doses in humans on the basis of comparative physiological considerations (e.g., ventilatory parameters, regional lung surface areas). Additionally, if the exposure period was discontinuous, it is adjusted to reflect continuous exposure.

Applying uncertainty factors. The inhalation RfD is derived from the NOAEL by applying uncertainty factors similar to those listed above for oral RfDs. The UF of 10 is used when extrapolating from animals to humans, in addition to calculation of the human equivalent dose, to account for interspecific variability in sensitivity to the toxicant. The resulting RfD value for inhalation exposure is generally reported as a concentration in air (in mg/m^3 for continuous, 24 hour/day exposure), although it may be reported as a corresponding inhaled intake (in mg/kg-day). A human body weight of 70 kg and an inhalation rate of 20 m^3/day are used to convert between an inhaled intake expressed in units of mg/kg-day and a concentration in air expressed in mg/m^3.

7.2.4 DERIVATION OF A SUBCHRONIC RfD (RfD_s)

The chronic RfDs described above pertain to lifetime or other long-term exposures and may be overly protective if used to evaluate the potential for adverse health effects resulting from substantially less-than-lifetime exposures. For such situations, EPA has begun calculating toxicity values specifically for subchronic exposure durations, using a method similar to that outlined above for chronic RfDs. EPA's Environmental Criteria and Assessment Office develops

subchronic RfDs and, although they have been peer-reviewed by Agency and outside reviewers, RfDs values have not undergone verification by an intra-Agency workgroup (see Section 7.2.7). As a result, subchronic RfDs are considered interim rather than verified toxicity values and are not placed in IRIS.

Development of subchronic reference doses parallels the development of chronic reference doses in concept; the distinction is one of exposure duration. Appropriate studies are evaluated and a subchronic NOAEL is identified. The RfD_s is derived from the NOAEL by the application of UFs and MF as outlined above. When experimental data are available only for shorter exposure durations than desired, an additional uncertainty factor is applied. This is similar to the application of the uncertainty factor for duration differences when a chronic RfD is estimated from subchronic animal data. On the other hand, if subchronic data are missing and a chronic oral RfD derived from chronic data exists, the chronic oral RfD is adopted as the subchronic oral RfD. There is no application of an uncertainty factor to account for differences in exposure duration in this instance.

7.2.5 DERIVATION OF A DEVELOPMENTAL TOXICANT RfD (RfD_{dt})

In developing an RfD_{dt}, evidence is gathered regarding the potential of a substance to cause adverse effects in a developing organism as a result of exposure prior to conception (either parent), during prenatal development, or postnatally to the time of sexual maturation. Adverse effects can include death, structural abnormality, altered growth, and functional deficiencies. Maternal toxicity also is considered. The evidence is assessed, and the substance is assigned a weight-of-evidence designation according to the scheme outlined below and summarized in the box in the opposite column. In this scheme, three levels are used to indicate the assessor's degree of confidence in the data: definitive evidence, adequate evidence, and inadequate evidence. The definitive and adequate evidence categories are subdivided as to whether the evidence demonstrates the occurrence or the absence of adverse effects.

WEIGHT-OF-EVIDENCE SCHEME FOR DEVELOPMENTAL TOXICITY

- Definitive Evidence for:
  - Human Developmental Toxicity
  - No Apparent Human Developmental Toxicity
- Adequate Evidence for:
  - Potential Human Developmental Toxicity
  - No Apparent Potential Human Developmental Toxicity
- Inadequate Evidence for Determining Potential Human Developmental Toxicity

After the weight-of-evidence designation is assigned, a study is selected for the identification of a NOAEL. The NOAEL is converted to an equivalent human dose, if necessary, and divided by uncertainty factors similar to those used in the development of an oral RfD. It should be remembered that the RfD_{dt} is based on a short duration of exposure because even a single exposure at a critical time (e.g., during gestation) may be sufficient to produce adverse developmental effects and that chronic exposure is not a prerequisite for developmental toxicity to be manifested. Therefore, RfD_{dt} values are appropriate for evaluating single event exposures, which usually are not adjusted based on the duration of exposure. Additional information on the derivation of RfD_{dt} values is available in EPA's *Proposed Amendments to the Guidelines for the Health Assessment of Suspect Developmental Toxicants* (EPA 1989e).

7.2.6 ONE-DAY AND TEN-DAY HEALTH ADVISORIES

Reference values that may be useful for evaluating potential adverse effects associated with oral exposures of shorter duration have been developed by the Office of Drinking Water. These values are known as One-day and Ten-day Health Advisories, which are issued as nonregulatory guidance. Health Advisory values are concentrations of contaminants in drinking water at which adverse health effects would not be expected to occur for an exposure of the specified

duration. The Health Advisory values are based on data describing noncarcinogenic effects and are derived by dividing a NOAEL or LOAEL by the appropriate uncertainty and modifying factors. They are based on a 10-kg child assumed to drink 1 liter of water per day, and a margin of safety is included to protect sensitive members of the population. One-day and Ten-day Health Advisories do not consider any carcinogenic risk associated with the exposure even if the compound is a potential carcinogen. For additional information on the derivation of Health Advisory values, refer to the Agency's guidance document (EPA 1989c).

7.2.7 VERIFICATION OF RfDs

EPA has formed an RfD Workgroup composed of members from many EPA offices to verify existing Agency RfDs and to resolve conflicting toxicity assessments and toxicity values within the Agency. The Workgroup reviews the information regarding the derivation of an RfD for a substance and summarizes its evaluations, conclusions, and reservations regarding the RfD in a standardized summary form from one to several pages in length. This form contains information regarding the development of the RfD, such as the chosen effect levels and uncertainty factors, as well as a statement on the confidence that the evaluators have in the RfD itself, the critical study, and the overall data base (high, medium, or low). Once verified, these data evaluation summaries are entered into IRIS and are available for public access.

Workgroup-approved RfDs are referred to as verified RfDs. Those RfDs awaiting workgroup approval are referred to as interim RfDs. At the time of this manual's publication, only chronic RfDs are being verified. No workgroup has been established to verify subchronic RfDs or developmental RfDs.

ABSORBED VERSUS ADMINISTERED DOSE

Toxicity values -- for both noncarcinogenic and carcinogenic effects -- are generally calculated from critical effect levels based on administered rather than absorbed doses. It is important, therefore, to compare such toxicity values to exposure estimates expressed as intakes (corresponding to administered doses), not as absorbed doses. For the few toxicity values that have been based on absorbed doses, either the exposure estimate or the toxicity value should be adjusted to make the values comparable (i.e., compare exposures estimated as absorbed doses to toxicity values expressed as absorbed doses, and exposures estimated as intakes to toxicity values expressed as administered doses). See Appendix A for guidance on making adjustments for absorption efficiency.

7.3 TOXICITY ASSESSMENT FOR CARCINOGENIC EFFECTS

This section describes how the types of toxicity information presented in Section 7.1 are considered in the toxicity assessment for carcinogenic effects. A slope factor and the accompanying weight-of-evidence determination are the toxicity data most commonly used to evaluate potential human carcinogenic risks. The methods EPA uses to derive these values are outlined below. Additional information can be obtained by consulting EPA's *Guidelines for Carcinogen Risk Assessment* (EPA 1986a) and Appendix B to IRIS (EPA 1989a).

7.3.1 CONCEPT OF NONTHRESHOLD EFFECTS

Carcinogenesis, unlike many noncarcinogenic health effects, is generally thought to be a phenomenon for which risk evaluation based on presumption of a threshold is inappropriate. For carcinogens, EPA assumes that a small number of molecular events can evoke changes in a single cell that can lead to uncontrolled cellular proliferation and eventually to a clinical state of disease. This hypothesized mechanism for carcinogenesis is referred to as "nonthreshold" because there is believed to be essentially no level of exposure to such a chemical that does not pose a finite probability, however small, of generating a carcinogenic response. That is, no dose is thought to be risk-free. Therefore, in evaluating cancer risks, an effect threshold cannot be estimated. For carcinogenic effects, EPA uses a two-part evaluation in which the substance first is assigned a weight-of-evidence classification, and then a slope factor is calculated.

7.3.2 ASSIGNING A WEIGHT OF EVIDENCE

In the first step of the evaluation, the available data are evaluated to determine the likelihood that the agent is a human carcinogen. The evidence is characterized separately for human studies and animal studies as sufficient, limited, inadequate, no data, or evidence of no effect. The characterizations of these two types of data are combined, and based on the extent to which the agent has been shown to be a carcinogen in experimental animals or humans, or both, the agent is given a provisional weight-of-evidence classification. EPA scientists then adjust the provisional classification upward or downward, based on other supporting evidence of carcinogenicity (see Section 7.1.3). For a further description of the role of supporting evidence, see the EPA guidelines (EPA 1986a).

The EPA classification system for weight of evidence is shown in the box in the opposite column. This system is adapted from the approach taken by the International Agency for Research on Cancer (IARC 1982).

EPA WEIGHT-OF-EVIDENCE CLASSIFICATION SYSTEM FOR CARCINOGENICITY

Group	Description
A	Human carcinogen
B1 or B2	Probable human carcinogen
	B1 indicates that limited human data are available.
	B2 indicates sufficient evidence in animals and inadequate or no evidence in humans.
C	Possible human carcinogen
D	Not classifiable as to human carcinogenicity
E	Evidence of noncarcinogenicity for humans

7.3.3 GENERATING A SLOPE FACTOR[2]

In the second part of the evaluation, based on the evaluation that the chemical is a known or probable human carcinogen, a toxicity value that defines quantitatively the relationship between dose and response (i.e., the slope factor) is calculated. Slope factors are typically calculated for potential carcinogens in classes A, B1, and B2. Quantitative estimation of slope factors for the chemicals in class C proceeds on a case-by-case basis.

Generally, the slope factor is a plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used in risk assessments to estimate an upper-bound lifetime probability of an individual developing cancer as a result of exposure to a particular level of a potential carcinogen. Slope factors should always be accompanied by the weight-of-evidence classification to indicate the strength of the evidence that the agent is a human carcinogen.

Identifying the appropriate data set. In deriving slope factors, the available information about a chemical is evaluated and an appropriate data set is selected. In choosing appropriate data sets, human data of high quality are preferable to animal data. If animal data are used, the species that responds most similarly to humans (with respect to factors such as metabolism, physiology, and pharmacokinetics) is preferred. When no clear choice is possible, the most sensitive species is given the greatest emphasis. Occasionally, in situations where no single study is judged most appropriate, yet several studies collectively support the estimate, the geometric mean of estimates from all studies may be adopted as the slope. This practice ensures the inclusion of all relevant data.

Extrapolating to lower doses. Because risk at low exposure levels is difficult to measure directly either by animal experiments or by epidemiologic studies, the development of a slope factor generally entails applying a model to the available data set and using the model to extrapolate from the relatively high doses administered to experimental animals (or the exposures noted in epidemiologic studies) to the lower exposure levels expected for human contact in the environment.

A number of mathematical models and procedures have been developed to extrapolate from carcinogenic responses observed at high doses to responses expected at low doses. Different extrapolation methods may provide a reasonable fit to the observed data but may lead to large differences in the projected risk at low doses. In keeping with EPA's *Guidelines for Carcinogen Risk Assessment* (EPA 1986a) and the principles outlined in *Chemical Carcinogens: A Review of the Science and Its Associated Principles* (OSTP 1985), the choice of a low-dose extrapolation model is governed by consistency with current understanding of the mechanism of carcinogenesis, and not solely on goodness-of-fit to the observed tumor data. When data are limited and when uncertainty exists regarding the mechanisms of carcinogenic action, the EPA guidelines and OSTP principles suggest that models or procedures that incorporate low-dose linearity are preferred when compatible with the limited information available. EPA's guidelines recommend that the linearized multistage model be employed in the absence of adequate information to the contrary. Among the other models available are the Weibull, probit, logit, one-hit, and gamma multihit models, as well as various time-to-tumor models. Most of these models are less conservative (i.e., predict lower cancer potency) than the linearized multistage model. These concepts and models are shown graphically in EPA (1989g) and OTA (1981).

In general, after the data are fit to the appropriate model, the upper 95th percent confidence limit of the slope of the resulting dose-response curve is calculated. This value is known as the slope factor and represents an upper 95th percent confidence limit on the probability of a response per unit intake of a chemical over a lifetime (i.e., there is only a 5 percent chance that the probability of a response could be greater than the estimated value on the basis of the experimental data and model used). In some cases, slope factors based on human dose-response data are based on the "best" estimate instead of the upper 95th percent confidence limits. Because the dose-response curve generally is linear only in the low-dose region, the slope factor estimate only holds true for low doses. Information concerning the limitations on use of slope factors can be found in IRIS.

Determining equivalent human doses. When animal data are used as a basis for extrapolation, the human dose that is equivalent to the dose in the animal study is calculated using the assumption that different species are equally sensitive to the effects of a toxicant if they absorb the same amount of the agent (in milligrams) per unit of body surface area. This assumption is made only in the absence of specific information about the equivalent doses for the chemical in question. Because surface area is approximately proportional to the 2/3 power of body weight, the equivalent human dose (in mg/day, or other units of mass per unit time) is calculated by multiplying the animal dose (in identical units) by the ratio of human to animal body weights raised to the 2/3 power. (For animal doses expressed as mg/kg-day, the equivalent human dose, in the same units, is calculated by multiplying the animal dose by the ratio of animal to human body weights raised to the 1/3 power.)

When using animal inhalation experiments to estimate lifetime human risks for partially soluble vapors or gases, the air concentration (ppm) is generally considered to be the equivalent dose between species based on equivalent exposure times (measured as fractions of a lifetime). For inhalation of particulates or completely absorbed gases, the amount absorbed per unit of body surface area is considered to be the equivalent dose between species.

Summary of dose-response parameters. Toxicity values for carcinogenic effects can be expressed in several ways. The slope factor is usually, but not always, the upper 95th percent confidence limit of the slope of the dose-response curve and is expressed as $(mg/kg\text{-}day)^{-1}$. If the extrapolation model selected is the linearized multistage model, this value is also known as the q_1^*. That is:

Slope factor = risk per unit dose
= risk per mg/kg-day

Where data permit, slope factors listed in IRIS are based on absorbed doses, although to date many of them have been based on administered doses. (The qualifiers related to absorbed versus administered dose given in the box on page 7-10 apply to assessment of cancer risk as well as to assessment of potential noncarcinogenic effects.)

Toxicity values for carcinogenic effects also can be expressed in terms of risk per unit concentration of the substance in the medium where human contact occurs. These measures, called unit risks, are calculated by dividing the slope factor by 70 kg and multiplying by the inhalation rate (20 m^3/day) or the water consumption rate (2 liters/day), respectively, for risk associated with unit concentration in air or water. Where an absorption fraction less than 1.0 has been applied in deriving the slope factor, an additional conversion factor is necessary in the calculation of unit risk so that the unit risk will be on an administered dose basis. The standardized duration assumption for unit risks is understood to be continuous lifetime exposure. Hence, when there is no absorption conversion required:

$$\text{air unit risk} = \text{risk per ug/m}^3 = \text{slope factor} \times 1/70 \text{ kg} \times 20 \text{ m}^3\text{/day} \times 10^{-3}$$

$$\text{water unit risk} = \text{risk per ug/L} = \text{slope factor} \times 1/70 \text{ kg} \times 2 \text{ L/day} \times 10^{-3}$$

The multiplication by 10^{-3} is necessary to convert from mg (the slope factor, or q_1^*, is given in $(\text{mg/kg-day})^{-1}$) to ug (the unit risk is given in $(\text{ug/m}^3)^{-1}$ or $(\text{ug/L})^{-1}$).

7.3.4 VERIFICATION OF SLOPE FACTORS

EPA formed the Carcinogen Risk Assessment Verification Endeavor (CRAVE) Workgroup to validate Agency carcinogen risk assessments and resolve conflicting toxicity values developed by various program offices. Workgroup members represent many different EPA offices and are scientists experienced in issues related to both the qualitative and quantitative risk assessment of carcinogenic agents. Slope factors verified by CRAVE have undergone extensive peer review and represent an Agency consensus. CRAVE-verified review summaries (similar to RfD Workgroup summaries) are entered into the IRIS data base.

7.4 IDENTIFYING APPROPRIATE TOXICITY VALUES FOR SITE RISK ASSESSMENT

Using the methods outlined above, EPA has performed toxicity assessments for many chemicals found at Superfund sites and has made the results available for use. This section provides step-by-step methods for locating appropriate toxicity information, including numerical toxicity values, to be used in Superfund risk assessments. Because one's confidence in toxicity values depends heavily on the data base and the methods of extrapolation used in their development, guidance is also included for identifying the important information on which these values are based.

7.4.1 GATHER TOXICITY INFORMATION FOR CHEMICALS BEING EVALUATED

In the first step of the toxicity assessment, information is collected regarding the toxic effects that occur following exposure to the chemical being evaluated. Particular attention should be paid to the route of exposure, the frequency and length of exposure, and the doses at which the adverse effects are expected to occur. Chemicals having potential reproductive or developmental effects should be flagged. Later in the evaluation, special reference doses for developmental effects can be sought for these chemicals.

Several sources may provide useful toxicity information and references to primary literature, although only some of them should be used as sources for slope factors and reference doses (as explained below).

Integrated Risk Information System (IRIS).[3] IRIS is an EPA data base containing up-to-date health risk and EPA regulatory information for numerous chemicals. IRIS contains only those RfDs and slope factors that have been verified by the RfD or CRAVE Workgroups and consequently, is considered to be the preferred source of toxicity information. Information in IRIS supersedes all other sources. Only if information is not available in IRIS for the chemical being evaluated should the sources below be consulted. IRIS consists of a collection of computer files on individual chemicals. Existing information on the chemicals is updated as new

scientific data are reviewed. New files and new chemicals are added as information becomes available. These chemical files contain descriptive and quantitative information in the following categories:

- oral and inhalation chronic reference doses;
- oral and inhalation slope factors and unit risks for chronic exposure to carcinogens;
- Health Advisories from EPA's Office of Drinking Water;
- EPA regulatory action summaries; and
- supplemental data on acute health hazards and physical/chemical properties.

To ensure access to the most up-to-date chemical information, IRIS is only available on-line. For information on how to access this data base, call IRIS User Support at 513-569-7254 or see the *Federal Register* notice regarding the availability of IRIS (EPA 1988a).

Should EPA regional staff have specific technical or scientific questions about any verification workgroup's analysis of particular data cited in IRIS, the Agency contact for a particular chemical (identified at the end of each IRIS file) should be consulted. If new data are identified suggesting that existing IRIS information may be outdated, or if there is concern or disagreement about the overall findings of particular files, the Agency IRIS coordinator should be consulted. The IRIS coordinator can assist in making arrangements should discussions with a verification workgroup be needed.

Health Effects Assessment Summary Tables (HEAST). Formerly "The Quarterly" and associated references, HEAST is a tabular presentation of toxicity information and values for chemicals for which Health Effects Assessments (HEAs), Health and Environmental Effects Documents (HEEDs), Health and Environmental Effects Profiles (HEEPs), Health Assessment Documents (HADs), or Ambient Air Quality Criteria Documents (AAQCDs) have been prepared. HEAST summarizes interim (and some verified) RfDs and slope factors as well as other toxicity information for specific chemicals. In addition, HEAST directs readers to the most current sources of supporting toxicity information through an extensive reference section. Therefore, HEAST is especially helpful when verified information for a chemical is not in IRIS. HEAST, which is updated quarterly, also provides a valuable pointer system for identifying current references on chemicals that are not in IRIS.

HEAST can be obtained upon request from the Superfund Docket (FTS or 202-382-3046). The Docket will mail copies of HEAST to callers and place requestors on a mailing list to receive an updated version quarterly. HEAs, HEEDs, HEEPs, HADs, and AAQCDs referenced in HEAST are available through EPA's Center for Environmental Research Information (CERI) in Cincinnati, OH (513-569-7562 or FTS 684-7562) or the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (703-487-4650 or 800-336-4700).

EPA criteria documents. These documents include drinking water criteria documents, drinking water Health Advisory summaries, ambient water quality criteria documents, and air quality criteria documents, and contain general toxicity information that can be used if information for a chemical is not available through IRIS or the HEAST references. Criteria documents are available through NTIS at the address given above. Information on drinking water criteria documents can be obtained through the Safe Drinking Water Hotline (800-426-4791).

Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profiles. ATSDR is developing toxicological profiles for 275 hazardous substances found at Superfund sites. The first 200 substances to be addressed have been identified in *Federal Register* notices (EPA 1987, 1988b). These profiles contain general toxicity information and levels of exposure associated with lethality, cancer, genotoxicity, neurotoxicity, developmental and reproductive toxicity, immunotoxicity, and systemic toxicity (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, and dermal/ocular effects). Health effects in humans and animals are discussed by exposure route (i.e., oral, inhalation, and dermal) and

HIERARCHY OF TOXICITY INFORMATION

Because toxicity information may change rapidly and quickly become outdated, care should be taken to find the most recent information available. IRIS is updated monthly, provides verified RfDs and slope factors, and is the Agency's preferred source of toxicity information. Only if values are unavailable in IRIS should other information sources be consulted.

HEAST is the second most current source of toxicity information of importance to Superfund. Unlike IRIS, HEAST provides information regarding interim as well as verified RfDs and slope factors. Readers are directed to supporting toxicity information for interim and verified values in an extensive reference section of HEAST. HEAST information should only be sought for those chemicals not listed in IRIS.

Toxicity information, RfDs, and slope factors also can be found in other EPA documents. Although these values were developed by offices within the Agency, they have not necessarily been verified by the RfD or CRAVE Workgroups. The use of up-to-date verified information is preferred to the use of interim information and, therefore, toxicity information should be obtained from other EPA references only if information could not be found in IRIS or HEAST. Before using references other than those cited in IRIS or HEAST, check with ECAO at 513-569-7300 (FTS 684-7300) to see if more current information is available.

duration (i.e., acute, intermediate, and chronic). Also included in the profiles are chapters on physicochemical properties, environmental fate, potential for human exposure, analytical methods, and regulatory and advisory status. Contact NTIS at the address given on the previous page for further information on the status or availability of a particular profile.

EPA's Environmental Criteria and Assessment Office (ECAO). ECAO may be contacted at 513-569-7300 (FTS 684-7300) for general toxicological information as well as for technical guidance concerning route-to-route extrapolations, toxicity values for dermal exposures, and the evaluation of chemicals without toxicity values. The requestor should identify their need for a "rapid response request" (within 48 hours) for interim guidance on Superfund health-related issues. Contractors must give the name and address of their RPM or regional risk assessment contact before ECAO will respond. RPMs and regional contacts will be sent a copy of ECAO's response to the contractor.

Open literature. A primary literature search may be valuable for determining whether new data are available that may affect IRIS information.

7.4.2 DETERMINE TOXICITY VALUES FOR NONCARCINOGENIC EFFECTS (RfDs)

After general toxicity information for the chemicals of concern has been located, the next step is to identify the appropriate toxicity values to be used in evaluating noncarcinogenic effects associated with the specific exposures being assessed. First, by referring to the exposure information generated in Chapter 6, the exposure periods for which toxicity values are necessary and the exposure route for each chemical being evaluated should be determined. The appropriate toxicity values for the chemical for each exposure duration and route of exposure can then be identified using the sources listed above.

For Superfund risk assessments, chronic RfDs should be identified for evaluating exposure periods between seven years and a lifetime, subchronic RfDs for exposure periods between two weeks and seven years, and One- or Ten-day Health Advisories for oral exposure periods of less than two weeks. According to EPA (1988c), One-day Health Advisories are applicable to exposure periods as long as five days and Ten-day Health Advisories are applicable to exposure periods as long as two weeks. Developmental RfDs should be identified for evaluating single exposure events and other very short exposures (e.g., one day). Note that for some substances and some exposure situations, more than one of the toxicity values listed above may be needed to adequately assess potential noncarcinogenic effects.

Because carcinogens also commonly evoke noncarcinogenic effects, RfDs should be sought for all chemicals being carried through the risk assessment, including carcinogens. The RfDs derived for carcinogens, however, are based on noncancer effects and should not be assumed to

be protective against carcinogenicity. A sample format for summarizing RfDs and other toxicity values is shown in Exhibit 7-2. This information will be needed in the risk characterization step (see Exhibits 8-3 and 8-4).

7.4.3 DETERMINE TOXICITY VALUES FOR CARCINOGENIC EFFECTS (SLOPE FACTORS)

In this step of the toxicity assessment, appropriate toxicity values for evaluating the carcinogenic risks associated with exposure are identified. First, by referring to the exposure information generated in Chapter 6, the route of exposure for the potential carcinogens being evaluated should be identified. Slope factors for these chemicals can then be identified using the hierarchy of sources listed in the box on page 7-15. Slope factors for all potential carcinogens having a weight-of-evidence classification of A, B, or C should be sought. A notation of the EPA weight-of-evidence classification should always be included with the slope factor. A sample format for summarizing the required toxicity values is shown in Exhibit 7-3. This information will be needed in the risk characterization step (see Exhibit 8-2).

7.5 EVALUATING CHEMICALS FOR WHICH NO TOXICITY VALUES ARE AVAILABLE

If EPA-derived RfDs and slope factors are available for the chemicals being examined, these values should always be used in the risk assessment. Use of EPA-derived toxicity values prevents duplication of effort and ensures consistency among risk assessments. If EPA-derived toxicity values are not available, the following measures are recommended.

7.5.1 ROUTE-TO-ROUTE EXTRAPOLATION

For cases in which EPA-derived toxicity values are not available for the route of exposure being considered but are available for another route, EPA recommends contacting ECAO for guidance on route-to-route extrapolation. If toxicity information is not available from ECAO, a qualitative rather than quantitative evaluation of the chemical is recommended. The implications of the absence of this chemical from the risk estimate should be discussed in the uncertainty section.

7.5.2 DERMAL EXPOSURE

No RfDs or slope factors are available for the dermal route of exposure. In some cases, however, noncarcinogenic or carcinogenic risks associated with dermal exposure can be evaluated using an oral RfD or oral slope factor, respectively. EPA recommends contacting ECAO for guidance on appropriate methods for evaluating dermal exposure for specific chemicals; some general guidance for calculating intakes via the dermal route and making appropriate comparisons with oral RfD values is given in Appendix A. In brief, exposures via the dermal route generally are calculated and expressed as absorbed doses. These absorbed doses are compared to an oral toxicity value that has been adjusted, if necessary, so that it too is expressed as an absorbed dose.

It is inappropriate to use the oral slope factor to evaluate the risks associated with dermal exposure to carcinogens such as benz(a)pyrene, which cause skin cancer through a direct action at the point of application. These types of skin carcinogens and other locally active compounds must be evaluated separately from the above method; consult ECAO for guidance. Generally only a qualitative assessment of risks from dermal exposure to these chemicals is possible. This does not apply to carcinogens such as arsenic, which are believed to cause skin cancer through a systemic rather than local action.

If information is not available from ECAO, the assessor should describe the effects of the chemical qualitatively and discuss the implications of the absence of the chemical from the risk estimate in the uncertainty section of the risk assessment.

7.5.3 GENERATION OF TOXICITY VALUES

If EPA-derived toxicity values are unavailable but adequate toxicity studies are available, one may derive toxicity values using Agency methodology. Any such derivation should be done

EXHIBIT 7-2

EXAMPLE OF TABLE FORMAT FOR TOXICITY VALUES: POTENTIAL NONCARCINOGENIC EFFECTS

Chemical	Chronic RfD[a] (mg/kg-day)	Confidence Level[b]	Critical Effect	RfD Basis/ RfD Source	Uncertainty and Modifying Factors
Oral Route					
Phenol	0.6*	Medium	Kidney and liver effects	Water[c]/ IRIS	UF = 1,000[d] for H,A,S,L MF = 1
Nitrobenzene	0.0005*	Medium	Hematologic, adrenal, kidney, and liver effects	Water[c]/ IRIS	UF = 10,000 for H,A,S,L MF = 1
Inhalation Route					
.....	.....	.....	.....	.....	.....

* Values for illustration only.

[a] Similarly formatted tables also could be used for subchronic and shorter-term toxicity values.

[b] Confidence level from IRIS, either high, medium, or low.

[c] RfD expressed as administered dose in drinking water, with assumed absorption fraction of 1.0.

[d] Uncertainty adjustment of 1,000 used to represent combined H, A, S, and L extrapolations.

Uncertainty adjustments: H = variation in human sensitivity;
A = animal to human extrapolation;
S = extrapolation from subchronic to chronic NOAEL;
L = extrapolation from LOAEL to NOAEL.

EXHIBIT 7-3

EXAMPLE OF TABLE FORMAT FOR TOXICITY VALUES: POTENTIAL CARCINOGENIC EFFECTS

Chemical	Slope Factor (SF) $(mg/kg\text{-}day)^{-1}$	Weight-of-Evidence Classification	Type of Cancer[a]	SF Basis/ SF Source
Oral Route				
Benzene	0.029*	A*	Leukemia	Water[b]/ IRIS
Chlordane	1.3*	B2*	--	Water[b]/ IRIS
Inhalation Route				
.....	.....	.....	.....	.....

* Values for illustration only.

[a] Identify type(s) of cancer in this table for Class A carcinogens only.

[b] Slope factor based on administered dose in drinking water and assumed absorption fraction of 1.0.

in conjunction with the regional risk assessment contact, who will submit the derivation to ECAO for approval. Contact with ECAO should be established early in the process to eliminate any duplication of effort because ECAO may have information on the chemical being evaluated.

7.6 UNCERTAINTIES RELATED TO TOXICITY INFORMATION

Toxicity information for many of the chemicals found at Superfund sites is often limited. Consequently, there are varying degrees of uncertainty associated with the toxicity values calculated. Sources of uncertainty associated with toxicity values may include:

- using dose-response information from effects observed at high doses to predict the adverse health effects that may occur following exposure to the low levels expected from human contact with the agent in the environment;
- using dose-response information from short-term exposure studies to predict the effects of long-term exposures, and vice-versa;
- using dose-response information from animal studies to predict effects in humans; and
- using dose-response information from homogeneous animal populations or healthy human populations to predict the effects likely to be observed in the general population consisting of individuals with a wide range of sensitivities.

An understanding of the degree of uncertainty associated with toxicity values is an important part of interpreting and using those values. Therefore, as part of the toxicity assessment for Superfund sites, a discussion of the strength of the evidence of the entire range of principal and supporting studies should be included. The degree of confidence ascribed to a toxicity value is a function of both the quality of the individual study from which it was derived and the completeness of the supporting data base. EPA-verified RfDs found in IRIS are accompanied by a statement of the confidence that the evaluators have in the RfD itself, the critical study, and the overall data base. All EPA-verified slope factors are accompanied by a weight-of-evidence classification, which indicates the likelihood that the agent is a human carcinogen. The weight-of-evidence classification is based on the completeness of the evidence that the agent causes cancer in experimental animals and humans. These designations should be used as one basis for the discussion of uncertainty.

The discussion of uncertainty also should include an indication of the extent to which an analysis of the results from different studies give a consistent, plausible picture of toxicity. The greater the strength of the evidence, the greater one's confidence in the conclusions drawn. The following factors add to the strength of the evidence that the chemical poses a hazard to humans and should be considered:

- similar effects across species, strains, sex, and routes of exposure;
- clear evidence of a dose-response relationship;
- a plausible relationship among data on metabolism, postulated mechanism of action, and the effect of concern (see Section 7.1.3);
- similar toxicity exhibited by structurally related compounds (see Section 7.1.3); and
- some link between the chemical and evidence of the effect of concern in humans (see Section 7.1.1).

High uncertainty (low confidence; low strength of evidence) indicates that the toxicity value might change if additional chronic toxicity data become available. Low uncertainty (high confidence) is an indication that a value is less likely to change as more data become available, because there is consistency among the toxic responses observed in different species, sexes, study designs, or in dose-response relationships. The lower the uncertainty about toxicity values,

the more confidence a decision-maker can have in the risk assessment results. Often, high confidence is associated with values that are based on human data for the exposure route of concern.

7.7 SUMMARIZATION AND PRESENTATION OF THE TOXICITY INFORMATION

This section discusses methods for presenting toxicity information in the risk assessment document for the chemicals being evaluated.

7.7.1 TOXICITY INFORMATION FOR THE MAIN BODY OF THE TEXT

A short description of the toxic effects of each chemical carried through the assessment in non-technical language should be prepared for inclusion in the main body of the risk assessment. Included in this description should be information on the effects associated with exposure to the chemical and the concentrations at which the adverse effects are expected to occur in humans. Toxicity values should be accompanied by a brief description of the overall data base and the particular study from which the value was derived. In addition, a notation should be made of the critical effect and any uncertainty factors used in the calculation. For any RfD value obtained from IRIS, a notation of the degree of confidence associated with the determination should also be included. To aid in the risk characterization, it should be indicated if absorption efficiency was considered and also what exposure averaging periods are appropriate for comparison with the value.

Summary tables of toxicity values for all chemicals should be prepared for inclusion in the main body of the risk assessment report. RfDs in the table should be accompanied with the uncertainty factors used in their derivation, the confidence rating given in IRIS (if applicable), and a notation of the critical effect. Slope factors should always be accompanied by EPA's weight-of-evidence classification.

7.7.2 TOXICITY INFORMATION FOR INCLUSION IN AN APPENDIX

If toxicity values were derived in conjunction with the regional risk assessment contact and ECAO for chemicals lacking EPA-derived values, a technical documentation/justification of the method of derivation should be prepared and included in the appendix of the risk assessment report. Included in this explanation should be a description of the toxic effects of the chemical such as information regarding the noncarcinogenic, carcinogenic, mutagenic, reproductive, and developmental effects of the compound. Also presented should be brief descriptions (species, route of administration, dosages, frequency of exposure, length of exposure, and critical effect) of the studies from which the values were derived as well as the actual method of derivation. References for the studies cited in the discussion should be included.

ENDNOTES FOR CHAPTER 7

1. The MF is set less than one for a small number of substances to account for nutritional essentiality.

2. The slope factor is occasionally referred to as a cancer potency factor; however, use of this terminology is not recommended.

3. The quantitative risk values and supporting information found in IRIS represent a consensus judgement of EPA's Reference Dose Workgroup or Carcinogen Risk Assessment Verification Endeavor (CRAVE) Workgroup. These workgroups are composed of scientists from EPA's program offices and the Office of Research and Development. The concept of Agency-wide consensus is one of the most valuable aspects of IRIS.

REFERENCES FOR CHAPTER 7

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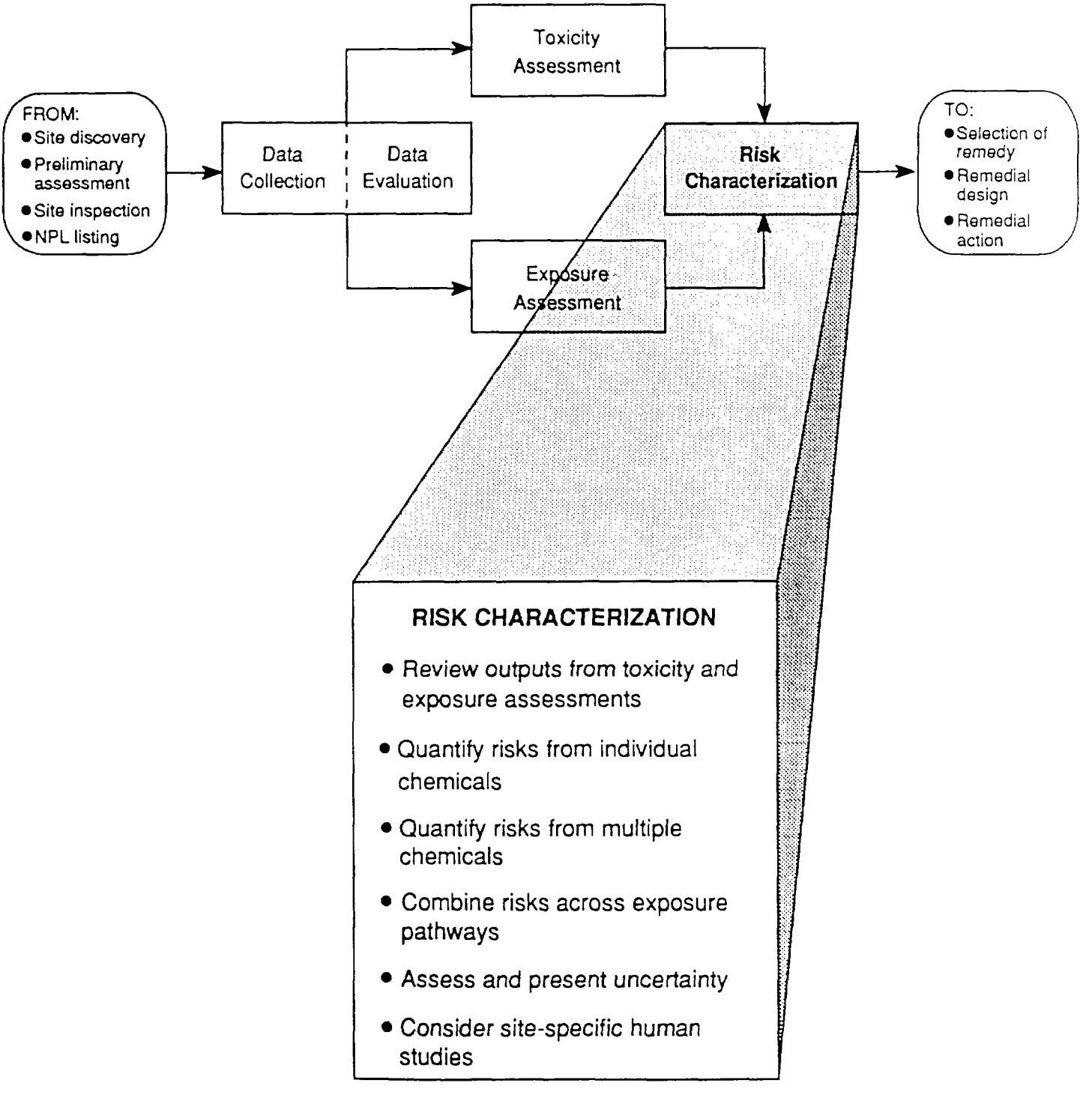
CHAPTER 8

RISK CHARACTERIZATION



CHAPTER 8

RISK CHARACTERIZATION

This chapter describes the final step of the baseline health risk assessment process, risk characterization. In this step, the toxicity and exposure assessments are summarized and integrated into quantitative and qualitative expressions of risk. To characterize potential noncarcinogenic effects, comparisons are made between projected intakes of substances and toxicity values; to characterize potential carcinogenic effects, probabilities that an individual will develop cancer over a lifetime of exposure are estimated from projected intakes and chemical-specific dose-response information. Major assumptions, scientific judgments, and to the extent possible, estimates of the uncertainties embodied in the assessment are also presented.

Risk characterization also serves as the bridge between risk assessment and risk management and is therefore a key step in the ultimate site decision-making process. This step assimilates risk assessment information for the risk manager (RPM or regional upper management involved in site decision-making) to be considered alongside other factors important for decision-making such as economics, technical feasibility, and regulatory context. The risk characterization methods described in this chapter are consistent with EPA's published risk assessment guidelines. Exhibit 8-1 is an overview of risk characterization, and illustrates how it relates to the preceding toxicity and exposure assessments and to the refinement of preliminary remediation goals.

In the following sections, the risk characterization methodology is described. There are separate discussions for carcinogenic and noncarcinogenic effects because the methodology differs for these two modes of chemical toxicity. In addition to giving instructions for calculating numerical estimates of risk, this chapter provides guidance for interpreting, presenting, and qualifying the results. A risk characterization cannot be considered complete unless the numerical expressions of risk are accompanied by explanatory text interpreting and qualifying the results.

8.1 REVIEW OF OUTPUTS FROM THE TOXICITY AND EXPOSURE ASSESSMENTS

Most sites being assessed will involve the evaluation of more than one chemical of concern and might include both carcinogenic and noncarcinogenic substances. The first step in risk characterization is to gather, review, compare, and organize the results of the exposure assessment (e.g., intakes for all exposure pathways and land-uses and for all relevant substances) and toxicity assessment (e.g., toxicity values for all exposure

ACRONYMS FOR CHAPTER 8

ARAR = Applicable or Relevant and Appropriate Requirement
ATSDR = Agency for Toxic Substances and Disease Registry
CDI = Chronic Daily Intake
ECAO = Environmental Criteria and Assessment Office
E = Exposure Level
HI = Hazard Index
IRIS = Integrated Risk Information System
LOAEL = Lowest-Observed-Adverse-Effect-Level
NOAEL = No-Observed-Adverse-Effect-Level
NRC = Nuclear Regulatory Commission
RfD = Reference Dose (when used without other modifiers, RfD generally refers to chronic reference dose)
RfD_{dt} = Developmental Reference Dose
RfD_s = Subchronic Reference Dose
RI/FS = Remedial Investigation/Feasibility Study
RME = Reasonable Maximum Exposure
SDI = Subchronic Daily Intake
SF = Slope Factor

DEFINITIONS FOR CHAPTER 8

Absorbed Dose. The amount of a substance penetrating the exchange boundaries of an organism after contact. Absorbed dose is calculated from the intake and the absorption efficiency. It usually is expressed as mass of a substance absorbed into the body per unit body weight per unit time (e.g., mg/kg-day).

Administered Dose. The mass of substance given to an organism and in contact with an exchange boundary (e.g., gastrointestinal tract) per unit body weight per unit time (e.g., mg/kg-day).

Chronic Reference Dose (RfD). An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime. Chronic RfDs are specifically developed to be protective for long-term exposure to a compound (as a Superfund program guideline, seven years to lifetime).

Developmental Reference Dose (RfD_{dt}). An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of an exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of development effects. Developmental RfDs are used to evaluate the effects of a single exposure event.

Exposure. Contact of an organism with a chemical or physical agent. Exposure is quantified as the amount of the agent available at the exchange boundaries of the organism (e.g., skin, lungs, gut) and available for absorption.

Exposure Assessment. The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure Pathway. The course a chemical or physical agent takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of intermedia transfer) also is included.

Exposure Route. The way a chemical or physical agent comes in contact with an organism (e.g., by ingestion, inhalation, dermal contact).

Hazard Index (HI). The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways. The HI is calculated separately for chronic, subchronic, and shorter-duration exposures.

Hazard Quotient. The ratio of a single substance exposure level over a specified time period (e.g., subchronic) to a reference dose for that substance derived from a similar exposure period.

Intake. A measure of exposure expressed as the mass of a substance in contact with the exchange boundary per unit body weight per unit time (e.g., mg chemical/kg body weight-day). Also termed the normalized exposure rate; equivalent to administered dose.

Integrated Risk Information System (IRIS). An EPA data base containing verified RfDs and slope factors and up-to-date health risk and EPA regulatory information for numerous chemicals. IRIS is EPA's preferred source for toxicity information for Superfund.

Reference Dose (RfD). The Agency's preferred toxicity value for evaluating noncarcinogenic effects result from exposures at Superfund sites. See specific entries for chronic RfD, subchronic RfD, and developmental RfD. The acronym RfD, when used without other modifiers, either refers generically to all types of RfDs or specifically to chronic RfDs; it never refers specifically to subchronic or developmental RfDs.

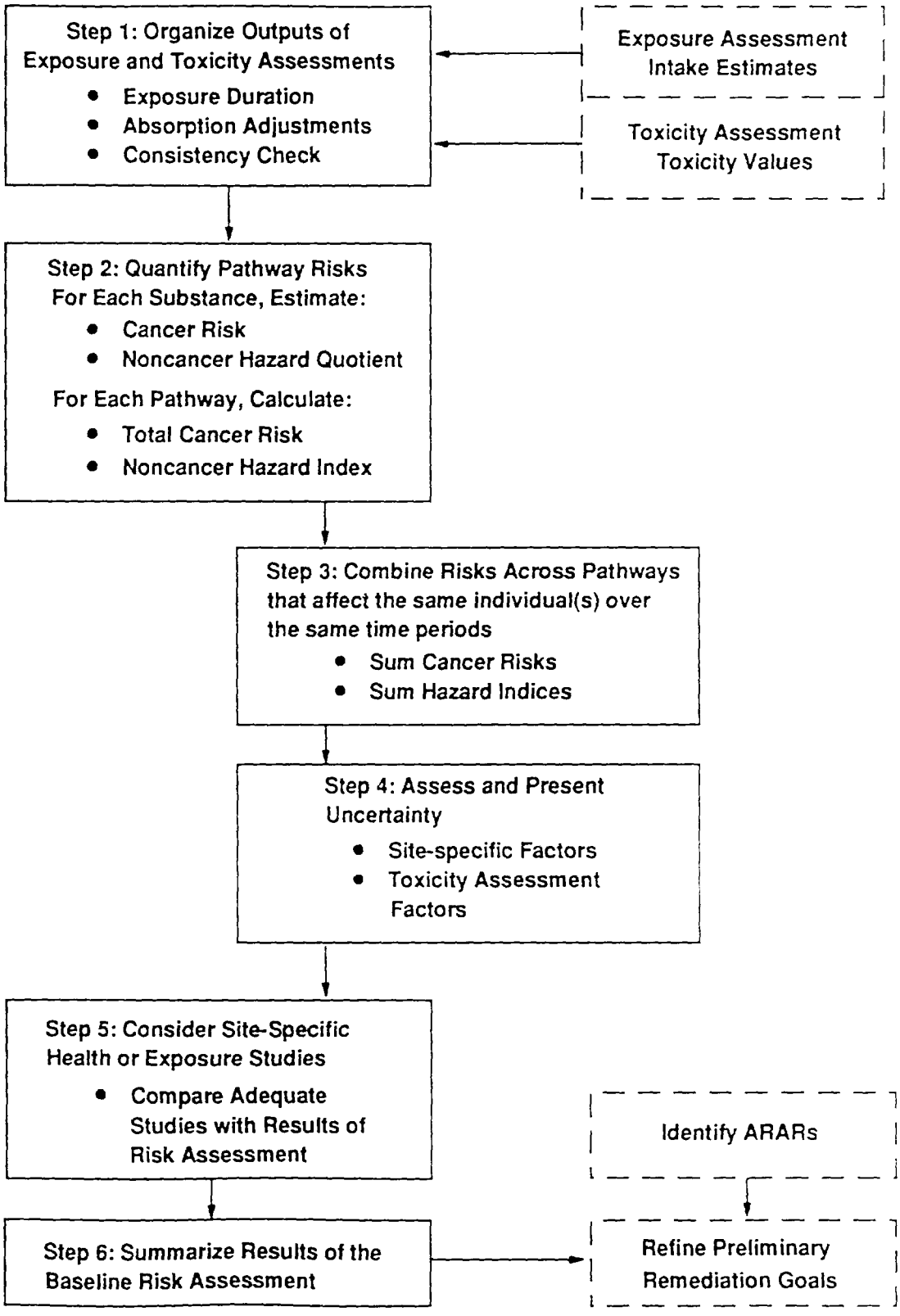
Slope Factor. A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.

Subchronic Reference Dose (RfD_s). An estimate (with uncertainty spanning perhaps an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a portion of a lifetime (as a Superfund program guideline, two weeks to seven years).

Weight-of-Evidence Classification. An EPA classification system for characterizing the extent to which the available data indicate that an agent is a human carcinogen. Recently, EPA has developed weight-of-evidence classification systems for some other kinds of toxic effects, such as developmental effects.

EXHIBIT 8-1

STEPS IN RISK CHARACTERIZATION



routes and relevant substances). The following two subsections describe how to organize the outputs from the exposure and toxicity assessments and how to check for the consistency and validity of the information from the preceding exposure and toxicity assessments.

8.1.1 GATHER AND ORGANIZE INFORMATION

For each exposure pathway and land use evaluated in the exposure assessment, check that all information needed to characterize risk is available. The necessary exposure information is outlined in the box below.

EXPOSURE INFORMATION NEEDED FOR RISK CHARACTERIZATION

- Estimated intakes (chronic, subchronic, and shorter-term, as appropriate) for chemicals.
- Important exposure modeling assumptions, including:
  - chemical concentration at the exposure points;
  - frequency and duration of exposure;
  - absorption assumptions; and
  - characterization of uncertainties.
- List of which exposure pathways can reasonably contribute to the exposure of the same individuals over the same time period.

For each chemical or substance evaluated in the toxicity assessment, use the checklist provided in the next box to ensure that all information needed to characterize risk is available.

8.1.2 MAKE FINAL CONSISTENCY AND VALIDITY CHECK

Check the consistency and validity of key assumptions common to the exposure outputs and the toxicity outputs for each contaminant and exposure pathway of concern. These assumptions include the averaging period for exposure, the exposure route, and the absorption adjustments. The basic principle is to ensure that the exposure

TOXICITY INFORMATION NEEDED FOR RISK CHARACTERIZATION

- Slope factors for all carcinogenic chemicals.
- Discussion of weight of evidence and classifications for all carcinogenic chemicals.
- Type of cancer for Class A carcinogens.
- Chronic and subchronic RfDs and shorter-term toxicity values (if appropriate) for all chemicals (including carcinogens and developmental toxicants).
- Critical effect associated with each RfD.
- Discussion of uncertainties, uncertainty factors, and modifying factor used in deriving each RfD and "degree of confidence" in RfD (i.e., high, medium, low).
- Whether the toxicity values are expressed as absorbed or administered doses.
- Pharmacokinetic data that may affect the extrapolation from animals to humans for both the RfD and slope factor.
- Uncertainties in any route-to-route extrapolations.

estimates correspond as closely as possible with the assumptions used in developing the toxicity values.

Averaging period for exposure. If the toxicity value is based on average lifetime exposure (e.g., slope factors), then the exposure duration must also be expressed in those terms. For estimating cancer risks, always use average lifetime exposure; i.e., convert less-than-lifetime exposures to equivalent lifetime values (see EPA 1986a, *Guidelines for Carcinogen Risk Assessment)*. On the other hand, for evaluating potential noncarcinogenic effects of less-than-lifetime exposures, do not compare chronic RfDs to short-term exposure estimates, and do not convert short-term exposures to equivalent lifetime values to compare with the chronic RfDs. Instead, use subchronic or shorter-term toxicity values to evaluate short-term exposures. Check that the estimated exposure duration is sufficiently similar to the duration of the exposure in the study used to identify the toxicity value to be protective of human health (particularly for subchronic and

shorter-term effects). A toxicologist should review the comparisons. In the absence of short-term toxicity values, the chronic RfD may be used as an initial screening value; i.e., if the ratio of the short-term exposure value to the chronic RfD is less than one, concern for potential adverse health effects is low. If this ratio exceeds unity, however, more appropriate short-term toxicity values are needed to confirm the existence of a significant health threat. ECAO may be consulted for assistance in finding short-term toxicity values.

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513-569-7300

Exposure route. Check that all toxicity values used for each exposure pathway being evaluated at the site are consistent with the route of exposure (e.g., oral to oral, inhalation to inhalation). It is not possible to extrapolate between exposure routes for some substances that produce localized effects dependent upon the route of exposure. For example, a toxicity value based on localized lung tumors that result only from inhalation exposure to a substance would not be appropriate for estimating risks associated with dermal exposure to the substance. At this time, EPA considers it appropriate only to extrapolate dermal toxicity values from values derived for oral exposure. It is not recommended that oral toxicity reference values be extrapolated casually from inhalation toxicity values, although this extrapolation may be performed on a case-by-case basis in consultation with ECAO. In general, inhalation values should not be extrapolated from oral values. (Also, see Section 7.5.1.)

Inhalation RfD_i values obtained from IRIS will usually be expressed as ambient air concentrations (i.e., mg/m^3), instead of as administered doses (i.e., mg/kg-day). It may be necessary, therefore, to calculate the RfDi in units of mg/kg-day for comparison with the intake estimated in the exposure assessment. The RfD_i expressed in mg/kg-day would be equal to the RfD_i in mg/m^3 multiplied by 20 m^3 air inhaled per person per day divided by 70 kg per person.

Absorption adjustment. Check that the exposure estimates and the toxicity values are either both expressed as absorbed doses or both expressed as intakes (i.e., administered doses). Except for the dermal route of exposure, the exposure estimates developed using the methods provided in Chapter 6 should be in the form of intakes, with no adjustments made for absorption. However, there are three types of absorption adjustments that might be necessary or appropriate depending on the available toxicity information. These are described below. Sample calculations for these absorption adjustments are provided in Appendix A.

(1) Dermal exposures. The output of the exposure assessment for dermal exposure is expressed as the amount of substance absorbed per kg body weight per day. It therefore may be necessary to derive an absorbed-dose toxicity value from an administered-dose toxicity value to compare with the exposure estimate. See Appendix A for sample calculations.

(2) Absorbed-dose toxicity value. For the substances for which the toxicity value is expressed as an absorbed rather than administered dose (e.g., inhalation slope factor in IRIS for trichloroethylene and several other substances), one should express exposure as an absorbed dose rather than as an intake. See Appendix A.

(3) Adjustment for medium of exposure. Adjusting for different relative absorption efficiencies based on the medium of exposure (e.g., food, soil, or water for oral exposure, vapor or particulates for inhalation exposure) is occasionally appropriate, but not generally recommended unless there are strong arguments for doing so. Many oral RfD and slope factor values assume ingestion in water even when based on studies that employed administration in corn oil by gavage or in feed. Thus, in most cases, the unadjusted toxicity value will provide a reasonable or conservative estimate of risk. See Appendix A.

8.2 QUANTIFYING RISKS

This section describes steps for quantifying risk or hazard indices for both carcinogenic and noncarcinogenic effects to be applied to each exposure pathway analyzed. The first subsection covers procedures for individual substances, and is followed by a subsection on procedures for quantifying risks associated with simultaneous exposures to several substances. Sample table formats for recording the results of these calculations as well as recording associated information related to uncertainty and absorption adjustments are provided in Exhibits 8-2 through 8-4.

8.2.1 CALCULATE RISKS FOR INDIVIDUAL SUBSTANCES

Carcinogenic effects. For carcinogens, risks are estimated as the incremental probability of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen (i.e., incremental or excess individual lifetime cancer risk). The guidelines provided in this section are consistent with EPA's (1986a) *Guidelines for Carcinogen Risk Assessment*. For some carcinogens, there may be sufficient information on mechanism of action that a modification of the approach outlined below is warranted. Alternative approaches may be considered in consultation with ECAO on a case-by-case basis.

The slope factor (SF) converts estimated daily intakes averaged over a lifetime of exposure directly to incremental risk of an individual developing cancer. Because relatively low intakes (compared to those experienced by test animals) are most likely from environmental exposures at Superfund sites, it generally can be assumed that the dose-response relationship will be linear in the low-dose portion of the multistage model dose-response curve. (See the Background Document 2 of IRIS for a discussion of the multistage model.) Under this assumption, the slope factor is a constant, and risk will be directly related to intake. Thus, the linear form of the carcinogenic risk equation is usually applicable for estimating Superfund site risks. This linear low-dose equation is described in the next box.

LINEAR LOW-DOSE CANCER RISK EQUATION

$$\text{Risk} = \text{CDI} \times \text{SF}$$

where:

Risk = a unitless probability (e.g., 2×10^{-5}) of an individual developing cancer;

CDI = chronic daily intake averaged over 70 years (mg/kg-day); and

SF = slope factor, expressed in $(\text{mg/kg-day})^{-1}$.

The CDI is identified in Exhibits 6-11 through 6-19 and 6-22 and the SF is identified in Exhibit 7-3.

However, this linear equation is valid only at low risk levels (i.e., below estimated risks of 0.01). For sites where chemical intakes might be high (i.e., risk above 0.01), an alternate calculation equation should be used. The one-hit equation, which is consistent with the linear low-dose model given above and described in the box on page 8-11, should be used instead.

Because the slope factor is often an upper 95th percentile confidence limit of the probability of response based on experimental animal data used in the multistage model, the carcinogenic risk estimate will generally be an upper-bound estimate. This means that EPA is reasonably confident that the "true risk" will not exceed the risk estimate derived through use of this model and is likely to be less than that predicted.

Noncarcinogenic effects. The measure used to describe the potential for noncarcinogenic toxicity to occur in an individual is not expressed as the probability of an individual suffering an adverse effect. EPA does not at the present time use a probabilistic approach to estimating the potential for noncarcinogenic health effects. Instead, the

EXHIBIT 8-2

EXAMPLE OF TABLE FORMAT FOR CANCER RISK ESTIMATES

Chemical	CDI (mg/kg-day)	CDI Adj. for Absorp.	SF $(mg/kg\text{-}day)^{-1}$	Weight of Evidence	Type of Cancer[a]	SF Source	SF Basis (Vehicle)	Chemical-specific Risk[b]	Total Pathway Risk[b]	Total Exposure Risk[b]
Exposure Pathway: Ingestion of Contaminated Private Well Water										
Benzene	0.00025*	No	0.029*	A*	Leukemia	HEA	Water[c]	$7x10^{-6}$		
Chlordane	0.00015*	No	1.3*	B2*		IRIS	Water[c]	$2x10^{-4}$		
									$2x10^{-4}$	
Exposure Pathway: Ingestion of Contaminated Fish										
Chlordane	0.00008*	No	1.3*	B2*		IRIS	Water[c]	$1x10^{-4}$		
									$1x10^{-4}$	
Nearby Residential Population in Area Y -- Total Cancer Risk (weight of evidence predominantly B2)[d]										$3x10^{-4}$

* Values for illustration only.
[a] Identify type of cancer in this table for Class A carcinogens only.
[b] All cancer risks should be expressed as one significant figure only.
[c] Slope factor based on dose administered in drinking water and assumed absorption fraction of 1.0.
[d] Summarize weight of evidence for carcinogens contributing most to the total cancer risk estimate.

SF = Slope Factor
CDI = Chronic Daily Intake

EXHIBIT 8-3

EXAMPLE OF TABLE FORMAT FOR CHRONIC HAZARD INDEX ESTIMATES

Chemical	CDI (mg/kg-day)	CDI Adjusted for Absorption	RfD (mg/kg-day)	Confidence Level	Critical Effect	RfD Source	RfD Basis (Vehicle)	RfD Uncertainty Adjustments	Modifying Factor	Hazard Quotient[a]	Pathway Hazard Index[a]	Total Exposure Hazard Index[a]
Exposure Pathway: Ingestion of Contaminated Private Well Water												
Phenol	0.1*	No	0.6*	M	Kidney, liver	IRIS	Water[c]	H,A,S,L*[d]	1*	0.2		
Nitrobenzene	0.0001*	No	0.0005*	M	Several	IRIS	Water[c]	H,A,S,L*	1*	0.2		
Cyanide	0.0003*	No	0.02*	M	Thyroid	IRIS	Water[c]	H,A*	5*	0.02	0.4[b]	
Exposure Pathway: Ingestion of Contaminated Fish												
Phenol	0.08*	Yes	0.6*	M	Kidney, liver	IRIS	Water[c]	H,A,S,L*[d]	1*	0.1		
MEK	0.005*	Yes	0.05*	M	CNS, fetotox	IRIS	Water[c]	H,A,S*	1*	0.1	0.2[b]	
Nearby Residential Population in Area Y -- Total Chronic Hazard Index												0.6[b]

* Values for illustration only.

[a] All hazard indices and hazard quotients should be expressed as one significant figure only.

[b] If the hazard index is greater than 1.0, see Section 8.2.2 for guidance on possible segregation of hazard index by endpoint.

[c] RfD expressed as administered dose.

[d] Uncertainty adjustment of 1,000 used to represent combined H, A, S, & L extrapolations.

Abbreviations for Uncertainty Adjustments: Factor of 10 used for each adjustment, unless indicated otherwise.

H = variation in human sensitivity
A = animal to human extrapolation
S = extrapolation from subchronic to chronic NOAEL
L = extrapolation from LOAEL to NOAEL

Confidence Level: L = low, M = medium, H = high.

MF = Modifying factor for EPA verified RfDs. This factor represents professional judgment on overall data base not specifically addressed by uncertainty adjustments.

CDI = Chronic Daily Intake
RfD = Chronic Reference Dose

EXHIBIT 8-4

EXAMPLE OF TABLE FORMAT FOR SUBCHRONIC HAZARD INDEX ESTIMATES

Chemical	SDI (mg/kg-day)	SDI Adjusted for Absorption	RfD_s (mg/kd-day)	Critical Effect	RfD_s Source	RfD_s Basis (Vehicle)	RfD_s Uncertainty Adjustments	Modifying Factor	Hazard Quotient[a]	Pathway Hazard Index[a]	Total Exposure Hazard Index[a]
Exposure Pathway: Ingestion of Contaminated Schoolyard Soil/Six Years											
Manganese	0.02*	Yes	0.5*	CNS, repro.	HEA	Water[c]	H, A*	1*	0.04		
Selenium	0.0008*	Yes	0.004*	Several	HEA	Water[c]	H, A*	1.5*	0.2		
Mercury	0.00001*	Yes	0.0003*	CNS	HEA	Water[c]	H*	1*	0.03		
Tin	0.006*	No	0.6*	Liver, kidney	HEA	Food[c]	H, A*	1*	0.01		
										0.3[b]	
Nearby Elementary Schoolyard -- Total Subchronic Hazard Index											0.3[b]

* Values for illustration only.

[a] All hazard indices and hazard quotients should be expressed as one significant figure only.

[b] If hazard index is greater than 1.0, see Section 8.2.2 for guidance on possible segregation of hazard index by endpoint.

[c] RfDs expressed as administered dose.

Abbreviations for Uncertainty Adjustments:
Factor of 10 used for each adjustment, unless indicated otherwise.

H = variation in human sensitivity
A = animal to human extrapolation
L = extrapolation from LOAEL to NOAEL

MF = Modifying factor for EPA RfD_ss. This factor represents professional judgment on overall data base not specifically addressed by uncertainty adjustments.

SDI = Subchronic Daily Intake
RfD_s = Subchronic Reference Dose

EXPLANATION OF SAMPLE TABLE FORMAT FOR CANCER RISK ESTIMATES

A sample table format for summarizing cancer risk estimates is provided in Exhibit 8-2. For each baseline risk assessment, at least two summary tables generally would be required: one for current land uses and one for future land uses. In the example provided in Exhibit 8-2, two exposure pathways were determined to contribute to exposure of a nearby residential population under current land use: ingestion of private well water contaminated with benzene and chlordane and ingestion of fish contaminated with chlordane. Moreover, a subset of the population in Area Y was exposed to the maximal well water contamination and consumed more locally caught fish than the remainder of the nearby population.

Values for the chronic daily intake (CDI), averaged over a lifetime, of each contaminant by each exposure pathway would be obtained from a table such as that shown in Exhibit 6-22. The CDI via well water was not adjusted for relative absorption efficiency because the slope factors for these substances assume ingestion in water and an absorption fraction of 1.0. The CDI for chlordane in fish was not adjusted for vehicle of exposure (i.e., food versus water) because absorption efficiency data were limited, and a relative absorption fraction of 1.0 was used as a conservative assumption. If, for example, available data had indicated that only 10 percent of chlordane ingested with fish is absorbed, the CDI could have been adjusted downward to 0.000008 mg/kg-day (i.e., 0.00008 mg/kg-day x 0.10 relative absorption fraction).

Values for the slope factors (SF), weight-of-evidence classification, type of cancer (for Class A carcinogens), reference source of the SF, and basis of the SF (vehicle of administration and absorption efficiency) would be obtained from a table such as that shown in Exhibit 7-3. The chemical-specific risks were calculated from the CDI and SF using the linear low-dose cancer risk equation (risk = CDI x SF). The total pathway risk for ingestion of private well water is the sum of the two chemical-specific risks for that pathway. The total risk estimate for the nearby residential population in area Y is the sum of the cancer risks for the two pathways. Note that it is important to summarize the weight of evidence for the carcinogens contributing most to the total cancer risk estimate; in this example, chlordane, a Class B2 carcinogen, accounted for most of the risk.

EXPLANATION OF SAMPLE TABLE FORMAT FOR CHRONIC HAZARD INDEX ESTIMATES

A sample table format for summarizing chronic hazard index estimates is provided in Exhibit 8-3. For each baseline risk assessment, at least two summary tables generally would be required: one for current land uses and one for future land uses. In the example provided in Exhibit 8-3, two exposure pathways were determined to contribute to exposure of a nearby residential population under current land use: ingestion of private well water contaminated with phenol, nitrobenzene, and cyanide and ingestion of fish contaminated with phenol and methyl ethyl ketone (MEK). Moreover, a subset of the population in Area Y was exposed to the maximal well water contamination and consumed more locally caught fish than the remainder of the nearby population.

Values for the chronic daily intake (CDI), averaged over the period of exposure, of each contaminant by each exposure pathway would be obtained from a table such as that shown in Exhibit 6-22. The CDI via well water was not adjusted for relative absorption efficiency because the RfDs for these substances are based on ingestion in water and an absorption fraction of 1.0. The CDI for phenol and MEK in fish was not adjusted for vehicle of exposure (i.e., food versus water) because absorption efficiency data were limited, and a relative absorption fraction of 1.0 was used as a conservative assumption. If, for example, available data had indicated that only 20 percent of MEK ingested with fish is absorbed, the CDI for MEK could have been adjusted downward to 0.001 mg/kg-day (i.e., 0.005 mg/kg-day x 0.20 relative absorption efficiency).

Values for the RfDs, confidence level in the RfD, critical effect, source of the value, and basis of the RfD (vehicle of administration and absorption efficiency) would be obtained from a table such as that shown in Exhibit 7-2. The chemical-specific hazard quotients are equal to the CDI divided by the RfD. The total pathway hazard index for ingestion of private well water is the sum of the three chemical-specific hazard quotients for that pathway. The total hazard index estimate for the nearby residential population in area Y is the sum of the hazard indices for the two exposure pathways.

Note that it is important to include the noncarcinogenic effects of carcinogenic substances when appropriate reference doses are available. For example, in an actual risk assessment of the chemicals summarized in Exhibit 6-22, the potential noncarcinogenic effects of chlordane should be evaluated and appropriate entries made in tables such as those shown in Exhibits 7-2 and 8-3.

ONE-HIT EQUATION FOR HIGH CARCINOGENIC RISK LEVELS

$$Risk = 1 - \exp(-CDI \times SF)$$

where:

Risk = a unitless probability (e.g., 2×10^{-5}) of an individual developing cancer;

exp = the exponential;

CDI = chronic daily intake averaged over 70 years (mg/kg-day); and

SF = slope factor, in $(mg/kg\text{-}day)^{-1}$.

NONCANCER HAZARD QUOTIENT

Noncancer Hazard Quotient = E/RfD

where:

E = exposure level (or intake);

RfD = reference dose; and

E and RfD are expressed in the same units and represent the same exposure period (i.e., chronic, subchronic, or shorter-term).

potential for noncarcinogenic effects is evaluated by comparing an exposure level over a specified time period (e.g., lifetime) with a reference dose derived for a similar exposure period. This ratio of exposure to toxicity is called a hazard quotient and is described in the box in the opposite column.

The noncancer hazard quotient assumes that there is a level of exposure (i.e., RfD) below which it is unlikely for even sensitive populations to experience adverse health effects. If the exposure level (E) exceeds this threshold (i.e., if E/RfD exceeds unity), there may be concern for potential noncancer effects. As a rule, the greater the value of E/RfD above unity, the greater the level of concern. Be sure, however, not to interpret ratios of E/RfD as statistical probabilities; a ratio of 0.001 does not mean that there is a one in one thousand chance of the effect occurring. Further, it is important to emphasize that the level of concern does not increase linearly as the RfD is approached or exceeded because RfDs do not have equal accuracy or precision and are not based on the same severity of toxic effects. Thus, the slopes of the dose-response curve in excess of the RfD can range widely depending on the substance.

Three exposure durations that will need separate consideration for the possibility of adverse noncarcinogenic health effects are chronic, subchronic, and shorter-term exposures. As guidance for Superfund, chronic exposures for humans range in duration from seven years to a lifetime; such long-term exposures are almost always of concern for Superfund sites (e.g., inhabitants of nearby residences, year-round users of specified drinking water sources). Subchronic human exposures range in duration from two weeks to seven years (as a Superfund program guideline) and are often of concern at Superfund sites. For example, children might attend a junior high school near the site for no more than two or three years. Exposures less than two weeks in duration are occasionally of concern at Superfund sites. For example, if chemicals known to be developmental toxicants are present at a site, short-term exposures of only a day or two can be of concern.

8.2.2 AGGREGATE RISKS FOR MULTIPLE SUBSTANCES

At most Superfund sites, one must assess potential health effects of more than one chemical (both carcinogens and other toxicants). Estimating risk or hazard potential by considering one chemical at a time might significantly underestimate the risks associated with simultaneous exposures to several substances. To assess the overall potential for cancer and noncancer effects posed by multiple chemicals, EPA (1986b) has developed *Guidelines for the Health Risk Assessment of Chemical Mixtures* that can also be applied to the case of simultaneous exposures to several chemicals from a variety of

sources by more than one exposure pathway. Although the calculation procedures differ for carcinogenic and noncarcinogenic effects, both sets of procedures assume dose additivity in the absence of information on specific mixtures.

Information on specific mixtures found at Superfund sites is rarely available. Even if such data exist, they are often difficult to use. Monitoring for "mixtures" or modeling the movement of mixtures across space and time present technical problems given the likelihood that individual components will behave differently in the environment (i.e., fate and transport). If data are available on the mixtures present at the site, but are not adequate to support a quantitative evaluation, note the information in the "assumptions" documentation.

Carcinogenic effects. The cancer risk equation described in the box below estimates the incremental individual lifetime cancer risk for simultaneous exposure to several carcinogens and is based on EPA's (1986a,b) risk assessment guidelines. This equation represents an approximation of the precise equation for combining risks which accounts for the joint probabilities of the same individual developing cancer as a consequence of exposure to two or more carcinogens.[1] The difference between the precise equation and the approximation described in the box is negligible for total cancer risks less than 0.1. Thus, the simple additive equation is appropriate for most Superfund risk assessments.

CANCER RISK EQUATION FOR MULTIPLE SUBSTANCES

$$Risk_T = \Sigma\ Risk_i$$

where:

$Risk_T$ = the total cancer risk, expressed as a unitless probability; and

$Risk_i$ = the risk estimate for the i^{th} substance.

The risk summation techniques described in the box on this page and in the footnote assume that intakes of individual substances are small. They also assume independence of action by the compounds involved (i.e., that there are no synergistic or antagonistic chemical interactions and that all chemicals produce the same effect, i.e., cancer). If these assumptions are incorrect, over- or under-estimation of the actual multiple-substance risk could result.

Calculate a separate total cancer risk for each exposure pathway by summing the substance-specific cancer risks. Resulting cancer risk estimates should be expressed using one significant figure only. Obviously, the total cancer risk for each pathway should not exceed 1. Exhibit 8-2 provides a sample table format for presenting estimated cancer risks for specified exposure pathways in the "Total Pathway Risk" column.

There are several limitations to this approach that must be acknowledged. First, because each slope factor is an upper 95th percentile estimate of potency, and because upper 95th percentiles of probability distributions are not strictly additive, the total cancer risk estimate might become artificially more conservative as risks from a number of different carcinogens are summed. If one or two carcinogens drive the risk, however, this problem is not of concern. Second, it often will be the case that substances with different weights of evidence for human carcinogenicity are included. The cancer risk equation for multiple substances sums all carcinogens equally, giving as much weight to class B or C as to class A carcinogens. In addition, slope factors derived from animal data will be given the same weight as slope factors derived from human data. Finally, the action of two different carcinogens might not be independent. New tools for assessing carcinogen interactions are becoming available (e.g., Arcos *et al.* 1988), and should be considered in consultation with the RPM. The significance of these concerns given the circumstances at a particular site should be discussed and presented with the other information described in Section 8.6.

Noncarcinogenic effects. To assess the overall potential for noncarcinogenic effects posed by more than one chemical, a hazard index (HI) approach has been developed based on EPA's

(1986b) *Guidelines for Health Risk Assessment of Chemical Mixtures*. This approach assumes that simultaneous subthreshold exposures to several chemicals could result in an adverse health effect. It also assumes that the magnitude of the adverse effect will be proportional to the sum of the ratios of the subthreshold exposures to acceptable exposures. The hazard index is equal to the sum of the hazard quotients, as described in the box below, where E and the RfD represent the same exposure period (e.g., subchronic, chronic, or shorter-term). When the hazard index exceeds unity, there may be concern for potential health effects. While any single chemical with an exposure level greater than the toxicity value will cause the hazard index to exceed unity, for multiple chemical exposures, the hazard index can also exceed unity even if no single chemical exposure exceeds its RfD.

NONCANCER HAZARD INDEX

$$\text{Hazard Index} = E_1/RfD_1 + E_2/RfD_2 + \ldots + E_i/RfD_i$$

where:

E_i = exposure level (or intake) for the i^{th} toxicant;

RfD_i = reference dose for the i^{th} toxicant; and

E and RfD are expressed in the same units and represent the same exposure period (i.e., chronic, subchronic, or shorter-term).

It is important to calculate the hazard index separately for chronic, subchronic, and shorter-term exposure periods as described below. It is also important to remember to include RfDs for the noncancer effects of carcinogenic substances.

(1) Noncarcinogenic effects -- chronic exposures. For each chronic exposure pathway (i.e., seven year to lifetime exposure), calculate a separate chronic hazard index from the ratios of the chronic daily intake (CDI) to the chronic reference dose (RfD) for individual chemicals as described in the box below. Exhibit 8-3 provides a sample table format for recording these results in the "Pathway Hazard Index" column.

CHRONIC NONCANCER HAZARD INDEX

$$\text{Chronic Hazard Index} = CDI_1/RfD_1 + CDI_2/RfD_2 + \ldots + CDI_i/RfD_i$$

where:

CDI_i = chronic daily intake for the i^{th} toxicant in mg/kg-day, and

RfD_i = chronic reference dose for the i^{th} toxicant in mg/kg-day.

The CDI is identified in Exhibits 6-11 through 6-19 and 6-22 and the RfD is identified in Exhibit 7-2.

(2) Noncarcinogenic effects -- subchronic exposures. For each subchronic exposure pathway (i.e., two week to seven year exposure), calculate a separate subchronic hazard index from the ratios of the subchronic daily intake (SDI) to the subchronic reference dose (RfD_s) for individual chemicals as described in the box on the next page. Exhibit 8-4 provides a sample table format for recording these results in the "Pathway Hazard Index" column. Add only those ratios corresponding to subchronic exposures that will be occurring simultaneously.

(3) Noncarcinogenic effects -- less than two week exposures. The same procedure may be applied for simultaneous shorter-term exposures to several chemicals. For drinking water exposures, 1- and 10-day Health Advisories can be used as reference toxicity values. Depending on available data, a separate hazard index might also be calculated for developmental toxicants (using RfD_ds), which might cause adverse

SUBCHRONIC NONCANCER HAZARD INDEX

Subchronic
Hazard Index = $SDI_1/RfD_{s1} + SDI_2/RfD_{s2} + \ldots + SDI_i/RfD_{si}$

where:

SDI_i = subchronic daily intake for the i^{th} toxicant in mg/kg-day; and

RfD_{si} = subchronic reference dose for the i^{th} toxicant in mg/kg-day.

effects following exposures of only a few days. See *Guidelines for the Health Assessment of Suspect Developmental Toxicants* (EPA 1986c; EPA 1989) for further guidance.

There are several limitations to this approach that must be acknowledged. As mentioned earlier, the level of concern does not increase linearly as the reference dose is approached or exceeded because the RfDs do not have equal accuracy or precision and are not based on the same severity of effect. Moreover, hazard quotients are combined for substances with RfDs based on critical effects of varying toxicological significance. Also, it will often be the case that RfDs of varying levels of confidence that include different uncertainty adjustments and modifying factors will be combined (e.g., extrapolation from animals to humans, from LOAELs to NOAELs, from one exposure duration to another).

Another limitation with the hazard index approach is that the assumption of dose additivity is most properly applied to compounds that induce the same effect by the same mechanism of action. Consequently, application of the hazard index equation to a number of compounds that are not expected to induce the same type of effects or that do not act by the same mechanism, although appropriate as a screening-level approach, could overestimate the potential for effects. This possibility is generally not of concern if only one or two substances are responsible for driving the HI above unity. If the HI is greater than unity as a consequence of summing several hazard quotients of similar value, it would be appropriate to segregate the compounds by effect and by mechanism of action and to derive separate hazard indices for each group.

Segregation of hazard indices. Segregation of hazard indices by effect and mechanism of action can be complex and time-consuming because it is necessary to identify all of the major effects and target organs for each chemical and then to classify the chemicals according to target organ(s) or mechanism of action. This analysis is not simple and should be performed by a toxicologist. If the segregation is not carefully done, an underestimate of true hazard could result. Agency review of particularly complex or controversial cases can be requested of ECAO through the regional risk assessment support staff.

The procedure for recalculating the hazard index by effect and by mechanism of action is briefly described in the box on the next page. If one of the effect-specific hazard indices exceeds unity, consideration of the mechanism of action might be warranted. A strong case is required, however, to indicate that two compounds which produce adverse effects on the same organ system (e.g., liver), although by different mechanisms, should not be treated as dose additive. Any such determination should be reviewed by ECAO.

If there are specific data germane to the assumption of dose-additivity (e.g., if two compounds are present at the same site and it is known that the combination is five times more toxic than the sum of toxicities for the two compounds), then modify the development of the hazard index accordingly. Refer to the EPA (1986b) mixtures guidelines for discussion of a hazard index equation that incorporates quantitative interaction data. If data on chemical interactions are available, but are not adequate to support a quantitative assessment, note the information in the "assumptions" being documented for the site risk assessment.

PROCEDURE FOR SEGREGATION OF HAZARD INDICES BY EFFECT

Segregation of hazard indices requires identification of the major effects of each chemical, including those seen at higher doses than the critical effect (e.g., the chemical may cause liver damage at a dose of 100 mg/kg-day and neurotoxicity at a dose of 250 mg/kg-day). Major effect categories include neurotoxicity, developmental toxicity, reproductive toxicity, immunotoxicity, and adverse effects by target organ (i.e., hepatic, renal, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, and dermal/ocular effects). Although higher exposure levels may be required to produce adverse health effects other than the critical effect, the RfD can be used as the toxicity value for each effect category as a conservative and simplifying step.

INFORMATION SOURCES FOR SEGREGATION OF HAZARD INDICES

Of the available information sources, the ATSDR Toxicological Profiles are well suited in format and content to allow a rapid determination of additional health effects that may occur at exposure levels higher than those that produce the critical effect. Readers should be aware that the ATSDR definitions of exposure durations are somewhat different than EPA's and are independent of species; acute -- up to 14 days; intermediate -- more than 14 days to 1 year; chronic -- greater than one year. IRIS contains only limited information on health effects beyond the critical effect, and EPA criteria documents and HEAs, HEEPs, and HEEDs may not systematically cover all health effects observed at doses higher those associated with the most sensitive effects.

8.3 COMBINING RISKS ACROSS EXPOSURE PATHWAYS

This section gives directions for combining the multi-chemical risk estimates across exposure pathways and provides guidance for determining when such aggregation is appropriate.

In some Superfund site situations, an individual might be exposed to a substance or combination of substances through several pathways. For example, a single individual might be exposed to substance(s) from a hazardous waste site by consuming contaminated drinking water from a well, eating contaminated fish caught near the site, and through inhalation of dust originating from the site. The total exposure to various chemicals will equal the sum of the exposures by all pathways. One should not automatically sum risks from all exposure pathways evaluated for a site, however. The following subsections describe how to identify exposure pathways that should be combined and, for these, how to sum cancer risks and noncancer hazard indices across multiple exposure pathways.

8.3.1 IDENTIFY REASONABLE EXPOSURE PATHWAY COMBINATIONS

There are two steps required to determine whether risks or hazard indices for two or more pathways should be combined for a single exposed individual or group of individuals . The first is to identify reasonable exposure pathway combinations. The second is to examine whether it is likely that the same individuals would consistently face the "reasonable maximum exposure" (RME) by more than one pathway.

Identify exposure pathways that have the potential to expose the same individual or subpopulation at the key exposure areas evaluated in the exposure assessment, making sure to consider areas of highest exposure for each pathway for both current and future land uses (e.g., nearest downgradient well, nearest downwind receptor). For each pathway, the risk estimates and hazard indices have been developed for a particular exposure area and time period; they do not necessarily apply to other locations or time periods. Hence, if two pathways do not affect the same individual or subpopulation, neither pathway's individual risk estimate or hazard index affects the other, and risks should not be combined.

Once reasonable exposure pathway combinations have been identified, it is necessary to examine whether it is likely that the same individuals would consistently face the RME as estimated by the methods described in Chapter 6. Remember that the RME estimate for each exposure pathway includes many conservative and upper-bound parameter values and assumptions (e.g., upper 95th confidence limit on amount of water ingested, upper-bound duration of occupancy

of a single residence). Also, some of the exposure parameters are not predictable in either space or time (e.g., maximum downwind concentration may shift compass direction, maximum ground-water plume concentration may move past a well). For real world situations in which contaminant concentrations vary over time and space, the same individual may or may not experience the RME for more than one pathway over the same period of time. One individual might face the RME through one pathway, and a different individual face the RME through a different pathway. Only if you can explain why the key RME assumptions for more than one pathway apply to the same individual or subpopulation should the RME risks for more than one pathway be combined.

In some situations, it may be appropriate to combine one pathway's RME risks with other pathways' risk estimates that have been derived from more typical exposure parameter values. In this way, resulting estimates of combined pathway risks may better relate to RME conditions.

If it is deemed appropriate to sum risks and hazard indices across pathways, the risk assessor should clearly identify those exposure pathway combinations for which a total risk estimate or hazard index is being developed. The rationale supporting such combinations should also be clearly stated. Then, using the methods described in Sections 8.3.2 and 8.3.3, total cancer risk estimates and hazard indices should be developed for the relevant exposure areas and individuals (or subpopulations). For example, Exhibits 8-2 and 8-3 illustrate the combination of cancer risk estimates and chronic noncancer hazard indices, respectively, for a hypothetical nearby residential population exposed to contaminants from a site by two exposure pathways: drinking contaminated ground water from private wells and ingestion of contaminated fish caught in the local river. In this hypothetical example, it is "known" that the few families living next to the site consume more locally caught fish than the remaining community and have the most highly contaminated wells of the area.

The following two subsections describe how to sum risks and hazard indices for multiple exposure pathways for carcinogenic and noncarcinogenic substances, respectively.

8.3.2 SUM CANCER RISKS

First, sum the cancer risks for each exposure pathway contributing to exposure of the same individual or subpopulation. For Superfund risk assessments, cancer risks from various exposure pathways are assumed to be additive, as long as the risks are for the same individuals and time period (i.e., less-than-lifetime exposures have all been converted to equivalent lifetime exposures). This summation is described in the box below. The sample table format given in Exhibit 8-2 provides a place to record the total cancer risk estimate.

CANCER RISK EQUATION FOR MULTIPLE PATHWAYS

Total Exposure Cancer Risk =

$$\text{Risk}(\text{exposure pathway}_1) + \text{Risk}(\text{exposure pathway}_2) + \ldots\ldots + \text{Risk}(\text{exposure pathway}_i)$$

As described in Section 8.2.2, although the exact equation for combining risk probabilities includes terms for joint risks, the difference between the exact equation and the approximation described above is negligible for total cancer risks of less than 0.1.

8.3.3 SUM NONCANCER HAZARD INDICES

To assess the overall potential for noncarcinogenic effects posed by several exposure pathways, the total hazard index for each exposure duration (i.e., chronic, subchronic, and shorter-term) should be calculated separately. This equation is described in the box on the next page. The sample table format given in Exhibit 8-3 provides a place to record the total exposure hazard index for chronic exposure durations.

When the total hazard index for an exposed individual or group of individuals exceeds unity, there may be concern for potential noncancer health effects. For multiple exposure pathways, the hazard index can exceed unity even if no single exposure pathway hazard index exceeds unity. If the total hazard index exceeds unity and

HAZARD INDEX EQUATION FOR MULTIPLE PATHWAYS

Total Exposure Hazard Index =

Hazard Index(exposure pathway$_1$) +
Hazard Index(exposure pathway$_2$) + ... +
Hazard Index(exposure pathway$_i$)

where:

Total Exposure Hazard Index is calculated separately for chronic, subchronic, and shorter-term exposure periods.

if combining exposure pathways has resulted in combining hazard indices based on different chemicals, one may need to consider segregating the contributions of the different chemicals according to major effect (see Section 8.2.2.).

8.4 ASSESSMENT AND PRESENTATION OF UNCERTAINTY

This section discusses practical approaches to assessing uncertainty in Superfund site risk assessments and describes ways to present key information bearing on the level of confidence in quantitative risk estimates for a site. The risk measures used in Superfund site risk assessments usually are not fully probabilistic estimates of risk, but conditional estimates given a considerable number of assumptions about exposure and toxicity (e.g., risk given a particular future land use). Thus, it is important to fully specify the assumptions and uncertainties inherent in the risk assessment to place the risk estimates in proper perspective. Another use of uncertainty characterization can be to identify areas where a moderate amount of additional data collection might significantly improve the basis for selection of a remedial alternative.

Highly quantitative statistical uncertainty analysis is usually not practical or necessary for Superfund site risk assessments for a number of reasons, not the least of which are the resource requirements to collect and analyze site data in such a way that the results can be presented as valid probability distributions. As in all environmental risk assessments, it already is known that uncertainty about the numerical results is generally large (i.e., on the range of at least an order of magnitude or greater). Consequently, it is more important to identify the key site-related variables and assumptions that contribute most to the uncertainty than to precisely quantify the degree of uncertainty in the risk assessment. Thus, the focus of this section is on qualitative/semi-quantitative approaches that can yield useful information to decision-makers for a limited resource investment.

There are several categories of uncertainties associated with site risk assessments. One is the initial selection of substances used to characterize exposures and risk on the basis of the sampling data and available toxicity information. Other sources of uncertainty are inherent in the toxicity values for each substance used to characterize risk. Additional uncertainties are inherent in the exposure assessment for individual substances and individual exposures. These uncertainties are usually driven by uncertainty in the chemical monitoring data and the models used to estimate exposure concentrations in the absence of monitoring data, but can also be driven by population intake parameters. Finally, additional uncertainties are incorporated in the risk assessment when exposures to several substances across multiple pathways are summed.

The following subsections describe how to summarize and discuss important site-specific exposure uncertainties and the more general toxicity assessment uncertainties.

8.4.1 IDENTIFY AND EVALUATE IMPORTANT SITE-SPECIFIC UNCERTAINTY FACTORS

Uncertainties in the exposure assessment typically include most of the site-specific uncertainties inherent in risk characterization, and thus are particularly important to summarize for each site. In risk assessments in general, and in the exposure assessment in particular, several sources of uncertainty need to be addressed: (1) definition of the physical setting, (2) model

applicability and assumptions, (3) transport, fate, and exposure parameter values, and (4) tracking uncertainty, or how uncertainties are magnified through the various steps of the assessment. Some of these sources of uncertainty can be quantified while others are best addressed qualitatively.

Definition of the physical setting. The initial characterization of the physical setting that defines the risk assessment for a Superfund site involves many professional judgments and assumptions. These include definition of the current and future land uses, identification of possible exposure pathways now and in the future, and selection of substances detected at the site to include in the quantitative risk assessment. In Superfund risk assessments, particular attention should be given to the following aspects of the definition of the physical setting.

- Likelihood of exposure pathways and land uses actually occurring. A large part of the risk assessment is the estimation of cancer risks or hazard indices that are conditional on the existence of the exposure conditions analyzed; e.g., if a residential development is built on the site 10 years from now, the health risks associated with contaminants from the site would be X. It is important to provide the RPM or other risk manager with information related to the likelihood that the assumed conditions will occur to allow interpretation of a conditional risk estimate in the proper context. For example, if the probability that a residential development would be built on the site 10 or 50 years from now is very small, different risk management decisions might be made than if the probability is high. Present the information collected during scoping and for the exposure assessment that will help the RPM to identify the relative likelihood of occurrence of each exposure pathway and land use, at least qualitatively (e.g., institutional land-use controls, zoning, regional development plans).

- The chemicals not included in the quantitative risk estimate as a consequence of missing information on health effects or lack of quantitation in the chemical analysis may represent a significant source of uncertainty in the final risk estimates. If chemicals with known health effects were eliminated from the risk assessment on the basis of concentration or frequency of detection, one should now review and confirm whether or not any of the chemicals previously eliminated should actually be included. For substances detected at the site, but not included in the quantitative risk assessment because of data limitations, discuss possible consequences of the exclusion on the risk assessment.

A checklist of uncertainty factors related to the definition of the physical setting is described in the box below.

LIST PHYSICAL SETTING DEFINITION UNCERTAINTIES

- For chemicals not included in the quantitative risk assessment, describe briefly:
  - reason for exclusion (e.g., quality control), and
  - possible consequences of exclusion on risk assessment (e.g., because of widespread contamination, underestimate of risk).
- For the current land uses describe:
  - sources and quality of information, and
  - qualitative confidence level.
- For the future land uses describe:
  - sources and quality of information, and
  - information related to the likelihood of occurrence.
- For each exposure pathway, describe why pathway was selected or not selected for evaluation (i.e., sample table format from Exhibit 6-8).
- For each combination of pathways, describe any qualifications regarding the selection of exposure pathways considered to contribute to exposure of the same individual or group of individuals over the same period of time.

Model applicability and assumptions. There is always some doubt as to how well an exposure model or its mathematical expression (e.g., ground-water transport model) approximates the true relationships between site-specific environmental conditions. Ideally, one would like to use a fully validated model that accounts for all the known complexities in the parameter

interrelationships for each assessment. At present, however, only simple, partially validated models are available and commonly used. As a consequence, it is important to identify key model assumptions (e.g., linearity, homogeneity, steady-state conditions, equilibrium) and their potential impact on the risk estimates. In the absence of field data for model validation, one could perform a limited sensitivity analysis (i.e., vary assumptions about functional relationships) to indicate the magnitude of uncertainty that might be associated with model form. At a minimum, one should list key model assumptions and indicate the potential impact of each on risk with respect to both direction and magnitude, as shown in the box below. A sample table format is presented in Exhibit 6-21 of Chapter 6.

CHARACTERIZE MODEL UNCERTAINTIES

- List/summarize the key model assumptions.
- Indicate the potential impact of each on risk:
  - direction (i.e., may over- or underestimate risk); and
  - magnitude (e.g., order of magnitude).

Parameter value uncertainty. During the course of a risk assessment, numerous parameter values are included in the calculations of chemical fate and transport and human intake. A first step in characterizing parameter value uncertainty in the baseline risk assessment is to identify the key parameters influencing risk. This usually can be accomplished by expert opinion or by an explicit sensitivity analysis. In a sensitivity analysis, the values of parameters suspected of driving the risks are varied and the degree to which changes in the input variables result in changes in the risk estimates are summarized and compared (e.g., the ratio of the change in output to the change in input). It is important to summarize the uncertainty associated with key parameters, as described below.

- Significant site data gaps might have required that certain parameter values be assumed for the risk assessment. For example, no information on the frequency with which individuals swim in a nearby stream might be available for a site, and an assumed frequency and duration of swimming events based on a national average could have driven the exposure estimate for this pathway.

- Significant data uncertainties might exist for other parameters, for example, whether or not the available soil concentration measurements are representative of the true distribution of soil contaminant concentrations.

Tracking uncertainty. Ideally, one would like to carry through the risk assessment the uncertainty associated with each parameter in order to characterize the uncertainty associated with the final risk estimates. A more practical approach for Superfund risk assessments is to describe qualitatively how the uncertainties might be magnified or biased through the risk models used. General quantitative, semi-quantitative, and qualitative approaches to uncertainty analysis are described below.

Quantitative approach. Only on the rare occasions that an RPM may indicate the need for a quantitative uncertainty analysis should one be undertaken. As mentioned earlier, a highly quantitative statistical uncertainty analysis is usually not practical or necessary for Superfund sites.

If a quantitative analysis is undertaken for a site, it is necessary to involve a statistician in the design and interpretation of that analysis. A quantitative approach to characterizing uncertainty might be appropriate if the exposure models are simple and the values for the key input parameters are well known. In this case, the first step would be to characterize the probability distributions for key input parameter values (either using measured or assumed distributions). The second step would be to propagate parameter value uncertainties through the analysis using analytic (e.g., first-order Taylor series approximation) or numerical (e.g., Monte Carlo simulation) methods, as appropriate. Analytic methods might be feasible if there are a few parameters with known distributions and linear relationships. Numerical methods (e.g., Monte

Carlo simulation) can be suitable for more complex relationships, but must be done on a computer and can be resource intensive even with time-saving techniques (e.g., Latin Hypercube sampling).

Two common techniques of propagating uncertainty are first-order analyses and Monte Carlo simulations. First-order analysis is based on the assumption that the total variance of a model output variable is a function of the variances of the individual model input variables and the sensitivity of the output variable to changes in input variables. The sensitivity of the output variable is defined by the first derivative of the function or model, which can be generated analytically or numerically. A Monte Carlo simulation estimates a distribution of exposures or risk by repeatedly solving the model equation(s). The probability distribution for each variable in the model must be defined. The computer selects randomly from each distribution every time the equation is solved. From the resulting output distribution of exposures or risk, the assessor can identify the value corresponding to any specified percentile (e.g., the 95th percentile in the exposure distribution).

These quantitative techniques require definition of the distribution of all input parameters and knowledge of the degree of dependence (i.e., covariance) among parameters. The value of first-order analyses or Monte Carlo simulations in estimating exposure or risk probability distributions diminishes sharply if one or more parameter value distributions are poorly defined or must be assumed. These techniques also become difficult to document and to review as the number of model parameters increases. Moreover, estimating a probability distribution for exposures and risks can lead one into a false sense of certainty about the analysis. Even in the most comprehensive analyses, it will generally be true that not all of the sources of uncertainty can be accounted for or all of the parameter codependencies recognized. Therefore, in addition to documenting all input distributions and covariances, it is very important to identify all of the assumptions and incomplete information that have not been accounted for in the quantitative uncertainty analysis (e.g., likelihood that a particular land use will occur) when presenting the results.

References describing numerical methods of propagating uncertainty through a risk analysis include Burmaster and von Stackelberg (1988), Hoffman and Gardner (1983), Iman and Helton (1988), and NRC (1983). References describing analytic methods of tracking uncertainty include Hoffman and Gardner (1983), NRC (1983), Downing *et al.* (1985), and Benjamin and Cornell (1970).

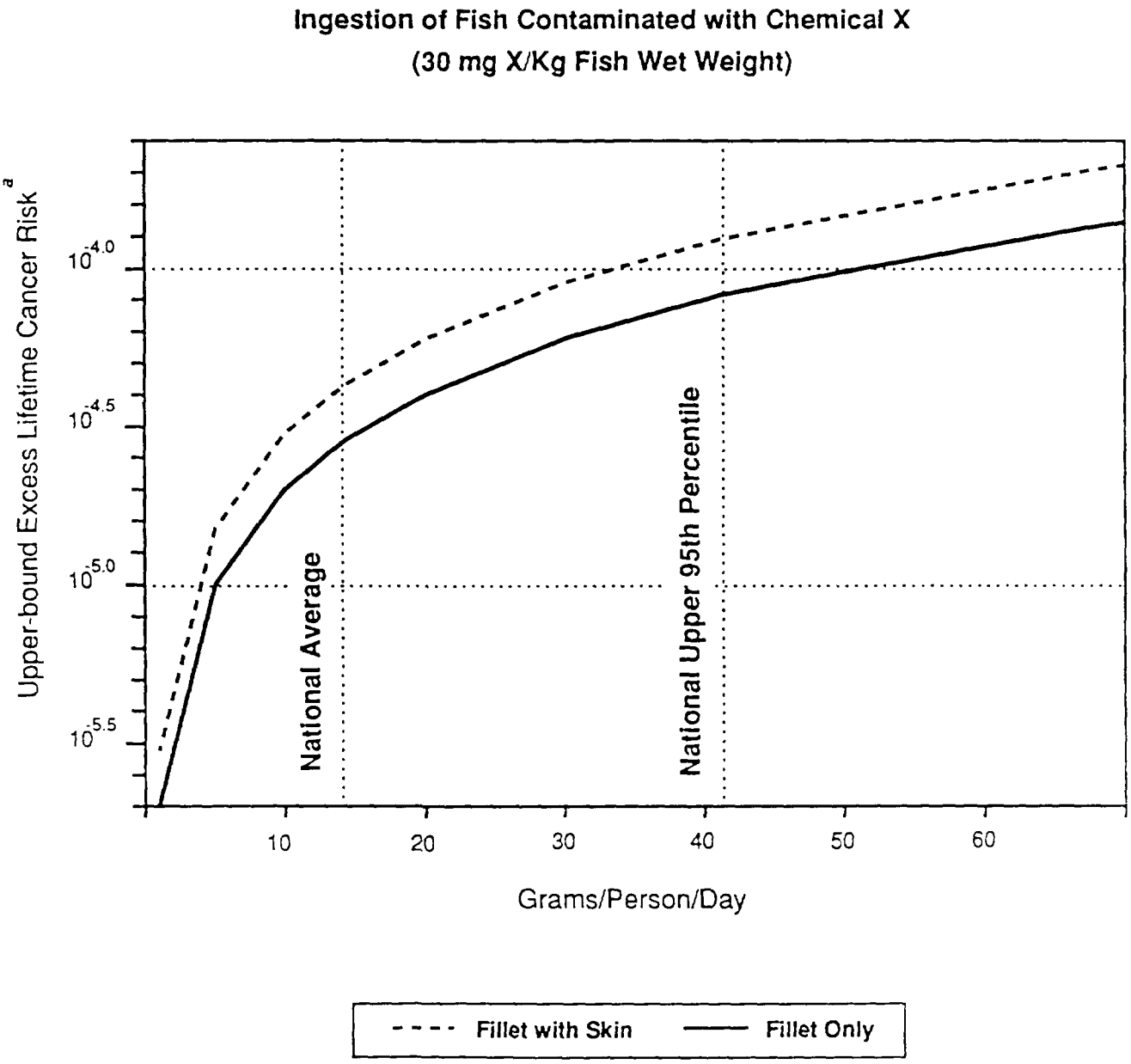
Semi-quantitative approach. Often available data are insufficient to fully describe parameter distributions, but are sufficient to describe the potential range of values the parameters might assume. In this situation, sensitivity analyses can be used to identify influential model input variables and to develop bounds on the distribution of exposure or risk. A sensitivity analysis can estimate the range of exposures or risk that result from combinations of minimum and maximum values for some parameters and mid-range values for others. The uncertainty for an assessment of this type could be characterized by presenting the ranges of exposure or risk generated by the sensitivity analysis and by describing the limitations of the data used to estimate plausible ranges of model input variables (EPA 1985).

Qualitative approach. Sometimes, a qualitative approach is the most practical approach to describing uncertainty in Superfund site risk assessments given the use of the information (e.g., identifying areas where the results may be misleading). Often the most practical approach to characterizing parameter uncertainty will be to develop a quantitative or qualitative description of the uncertainty for each parameter and to simply indicate the possible influence of these uncertainties on the final risk estimates given knowledge of the models used (e.g., a specific ground-water transport model). A checklist of uncertainty factors related to the definition of parameters is described in the box on page 8-22. A sample table format is provided in Exhibit 6-21 of Chapter 6.

Consider presentation of information on key parameter uncertainties in graphic form to illustrate clearly to the RPM or other risk managers the significance of various assumptions. For example, Exhibit 8-5 plots assumptions regarding contaminated fish ingestion and resulting

EXHIBIT 8-5

EXAMPLE OF PRESENTATION OF IMPACT OF EXPOSURE ASSUMPTIONS ON CANCER RISK ESTIMATE



[a] The risk of developing cancer is plotted on a log scale. A risk of 10^{-4} indicates a probability of 1 chance in 10,000 and a risk of 10^{-5} indicates a probability of 1 chance in 100,000 of an individual developing cancer.

impacts on the cancer risk estimate for this exposure pathway. Exhibit 8-6 illustrates the significance of these same assumptions for the hazard index estimates for contaminated fish consumption. Additionally, maps showing isopleths of risks resulting from modeled air exposures such as emissions near the site may assist the RPM or risk manager in visualizing the significance of current or future site risks for a community.

CHARACTERIZE FATE AND TRANSPORT AND EXPOSURE PARAMETER UNCERTAINTIES

- List all key exposure assessment parameters (e.g., infiltration rate, exposure duration, bioconcentration factors, body weight).
- List the value used for each parameter and rationale for its selection.
- Describe the measured or assumed parameter value distributions, if possible, considering:
  - total range;
  - shape of distribution, if known (e.g., log-normal);
  - mean (geometric or arithmetic) + standard deviation; and/or
  - specific percentiles (e.g., median, 95th).
- Quantify the uncertainty of statistical values used in the risk assessment (e.g., standard error of the mean) or data gaps and qualifiers.
- Describe potential direction and magnitude of bias in risk estimate resulting from assumptions or data gaps (see Exhibit 6-21).

8.4.2 IDENTIFY AND EVALUATE TOXICITY ASSESSMENT UNCERTAINTY FACTORS

For substances that contribute most to the estimates of cancer risk and noncancer hazard indices, summarize the uncertainty inherent in the toxicity values for the durations of exposure assessed. Some of the information (e.g., weight of evidence for potential human carcinogens, uncertainty adjustments for noncancer toxicity values) has already been recorded in the sample table formats provided in Exhibits 8-2 through 8-4. Other information will be developed during the toxicity assessment itself (see Chapter 7). The box on page 8-24 provides a checklist of uncertainties that apply to most toxicity assessments.

Multiple substance exposure uncertainties. Uncertainties associated with summing risks or hazard indices for several substances are of particular concern in the risk characterization step. The assumption of dose additivity ignores possible synergisms or antagonisms among chemicals, and assumes similarity in mechanisms of action and metabolism. Unfortunately, data to assess interactions quantitatively are generally lacking. In the absence of adequate information, EPA guidelines indicate that carcinogenic risks should be treated as additive and that noncancer hazard indices should also be treated as additive. These assumptions are made to help prevent an underestimation of cancer risk or potential noncancer health effects at a site.

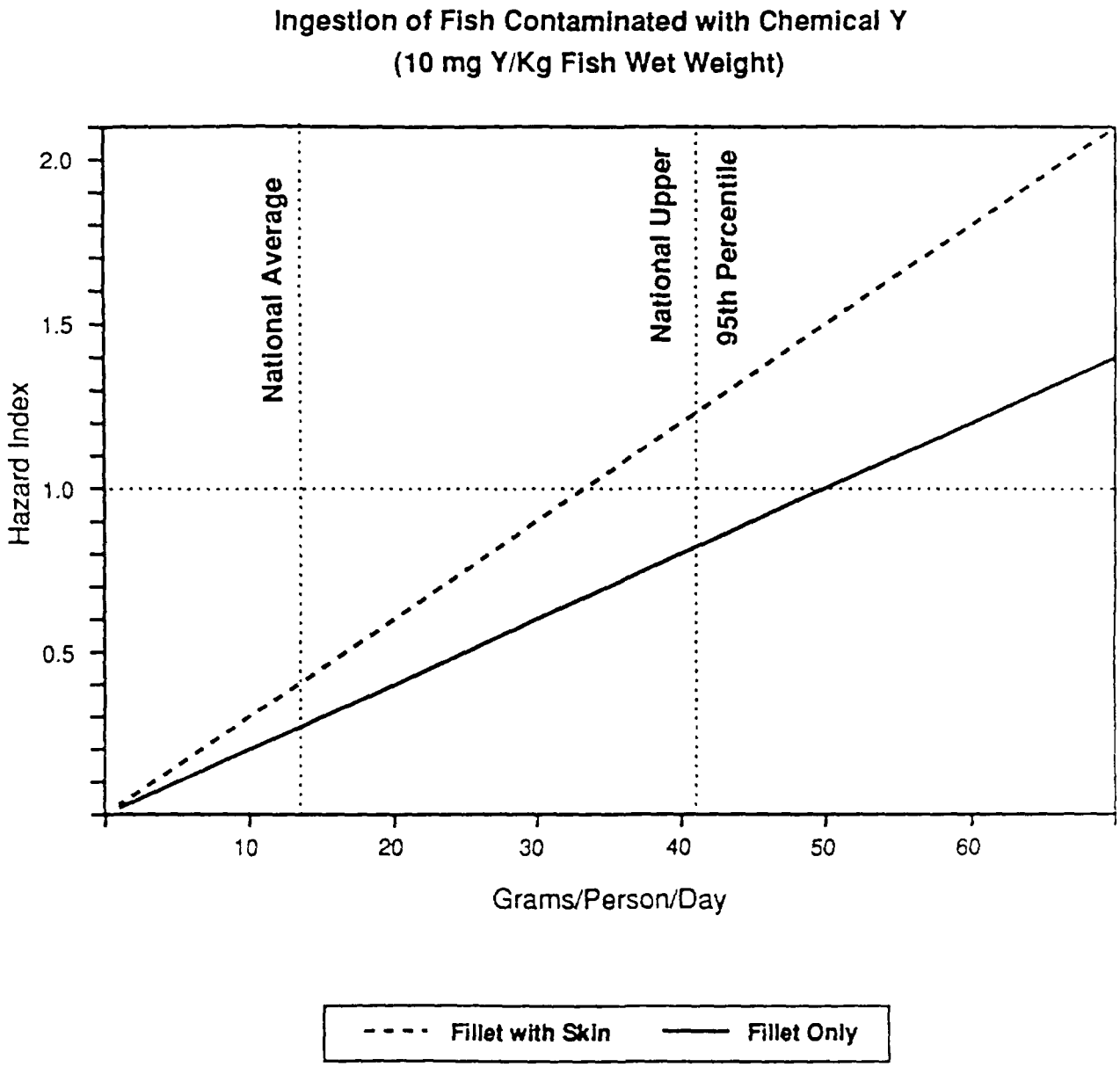
Be sure to discuss the availability of information concerning potential antagonistic or synergistic effects of chemicals for which cancer risks or hazard indices have been summed for the same exposed individual or subpopulations. On the basis of available information concerning target organ specificity and mechanism of action, indicate the degree to which treating the cancer risks as additive may over- or under-estimate risk. If only qualitative information is available concerning potential interactions or dose-additivity for the noncarcinogenic substances, discuss whether the information indicates that hazard indices may have been over- or under-estimated. This discussion is particularly important if the total hazard index for an exposure point is slightly below or slightly above unity, or if the total hazard index exceeds unity and the effect-specific hazard indices are less than unity, and if the uncertainty is likely to significantly influence the risk management decision at the site.

8.5 CONSIDERATION OF SITE-SPECIFIC HUMAN STUDIES

This section describes how to compare the results of the risk characterization step with

EXHIBIT 8-6

EXAMPLE OF PRESENTATION OF IMPACT OF EXPOSURE ASSUMPTIONS ON HAZARD INDEX ESTIMATE



ATSDR health assessments and other site-specific human studies that might be available. The first subsection outlines how to compare an ATSDR health assessment for the site with the risk results summarized in the previous sections (Sections 8.2, 8.3, and 8.4). The second subsection discusses when epidemiological or health studies might provide useful information for assessing exposures and health risks associated with contaminants from a site.

CHARACTERIZE TOXICITY ASSESSMENT UNCERTAINTIES

For each substance carried through the quantitative risk assessment, list uncertainties related to:

- qualitative hazard findings (i.e., potential for human toxicity);
- derivation of toxicity values, e.g.,
  - human or animal data,
  - duration of study (e.g., chronic study used to set subchronic RfD), and
  - any special considerations;
- the potential for synergistic or antagonistic interactions with other substances affecting the same individuals; and
- calculation of lifetime cancer risks on the basis of less-than-lifetime exposures.

For each substance not included in the quantitative risk assessment because of inadequate toxicity information, list:

- possible health effects; and
- possible consequences of exclusion on final risk estimates.

8.5.1 COMPARE WITH ATSDR HEALTH ASSESSMENT

ATSDR health assessments were defined and compared to the RI/FS risk assessment in Section 2.2.2. As of 1989, preliminary ATSDR health assessments should be completed before the RI/FS risk assessment is initiated and therefore should be available to the risk assessor as early as "scoping." The steps for comparing the preliminary ATSDR health assessment with the baseline risk assessment are outlined below.

Review again the ATSDR health assessment findings and conclusions. These will be largely qualitative in nature. If the ATSDR health assessment identifies exposure pathways or chemicals of concern that have not been included in the RI/FS baseline risk assessment, describe the information supporting the decision not to include these parameters. If there are differences in the qualitative conclusions of the health assessment and the quantitative conclusions of the baseline risk assessment, explain the differences, if possible, and discuss their implications.

8.5.2 COMPARE WITH OTHER AVAILABLE SITE-SPECIFIC EPIDEMIOLOGICAL OR HEALTH STUDIES

For most Superfund sites, studies of human exposure or health effects in the surrounding population will not be available. However, if controlled epidemiological or other health studies have been conducted, perhaps as a consequence of the preliminary ATSDR health assessment or other community involvement, it is important to include this information in the baseline risk assessment as appropriate. However, not all such studies provide meaningful information in the context of Superfund risk assessments.

One can determine the availability of other epidemiological or health studies for populations potentially exposed to contaminants from the site by contacting the ATSDR Regional Representative, the Centers for Disease Control in Atlanta, Georgia, and state and local health agencies as early in the risk assessment process as possible. It is important to avoid use of anecdotal information or data from studies that might include a significant bias or confounding factor, however. Isolated reports of high body levels of substances that are known to be present at the site in a few individuals living near the site are not sufficient evidence to confirm the hypothesis that these individuals have received significant exposures from the site. Nor can isolated reports of disease or symptoms in a few individuals living near the site be used to confirm the hypothesis that the cause of the health effects in these individuals was exposure to contamination from the site. A trained epidemiologist should review

any available studies in order to identify possible study limitations and implications for site risk findings. The small populations and variable exposures predominating at most Superfund sites will make it extremely difficult to detect site-related effects using epidemiological techniques.

If site-specific health or exposure studies have been identified and evaluated as adequate, one should incorporate the study findings into the overall risk characterization to strengthen the conclusions of the risk assessment (e.g., the risk assessment predicts elevated blood lead levels and the human exposure study documented elevated blood lead levels only among those exposed to ground water contaminated by the site). Because of the generally large and different types of uncertainties associated with the risk assessment and actual health studies, a qualitative, not quantitative, comparison between the two types of studies is generally warranted. Areas of agreement and disagreement between the health study(ies) and the risk assessment should be described and factors that might contribute to any disagreement discussed.

8.6 SUMMARIZATION AND PRESENTATION OF THE BASELINE RISK CHARACTERIZATION RESULTS

This section provides guidance on interpreting and presenting the risk characterization results. The results of the baseline evaluation should not be taken as a characterization of absolute risk. An important use of the risk and hazard index estimates is to highlight potential sources of risk at a site so that they may be dealt with effectively in the remedial process. It is the responsibility of the risk assessment team to develop conclusions about the magnitude and kinds of risk at the site and the major uncertainties affecting the risk estimates. It is not the responsibility of the risk assessment team to evaluate the significance of the risk in a program context, or whether and how the risk should be addressed, which are risk management decisions.

The ultimate user of the risk characterization results will be the RPM or other risk manager for the site. This section therefore outlines a presentation of material that is designed to assist the risk manager in using risk information to reach site-specific decisions.

8.6.1 SUMMARIZE RISK INFORMATION IN TEXT

The final discussion of the risk characterization results is a key component of the risk characterization. The discussion provides a means of placing the numerical estimates of risk and hazard in the context of what is known and what is not known about the site and in the context of decisions to be made about selection of remedies. At a minimum, the discussion should include:

- confidence that the key site-related contaminants were identified and discussion of contaminant concentrations relative to background concentration ranges;
- a description of the various types of cancer and other health risks present at the site (e.g., liver toxicity, neurotoxicity), distinguishing between known effects in humans and those that are predicted to occur based on animal experiments;
- level of confidence in the quantitative toxicity information used to estimate risks and presentation of qualitative information on the toxicity of substances not included in the quantitative assessment;
- level of confidence in the exposure estimates for key exposure pathways and related exposure parameter assumptions;
- the magnitude of the cancer risks and noncancer hazard indices relative to the Superfund site remediation goals in the NCP (e.g., the cancer risk range of 10^{-4} to 10^{-7} and noncancer hazard index of 1.0);
- the major factors driving the site risks (e.g., substances, pathways, and pathway combinations);
- the major factors reducing the certainty in the results and the significance of these uncertainties (e.g., adding risks over several substances and pathways);

- exposed population characteristics; and
- comparison with site-specific health studies, when available.

In addition, if the size of the potentially exposed population is large, the presentation of population numbers may be of assistance to the RPM, especially in evaluating risks in the context of current land use. Individual risk estimates based on the reasonable maximum exposure (RME) should not be presented as representative of a broadly defined population, however.

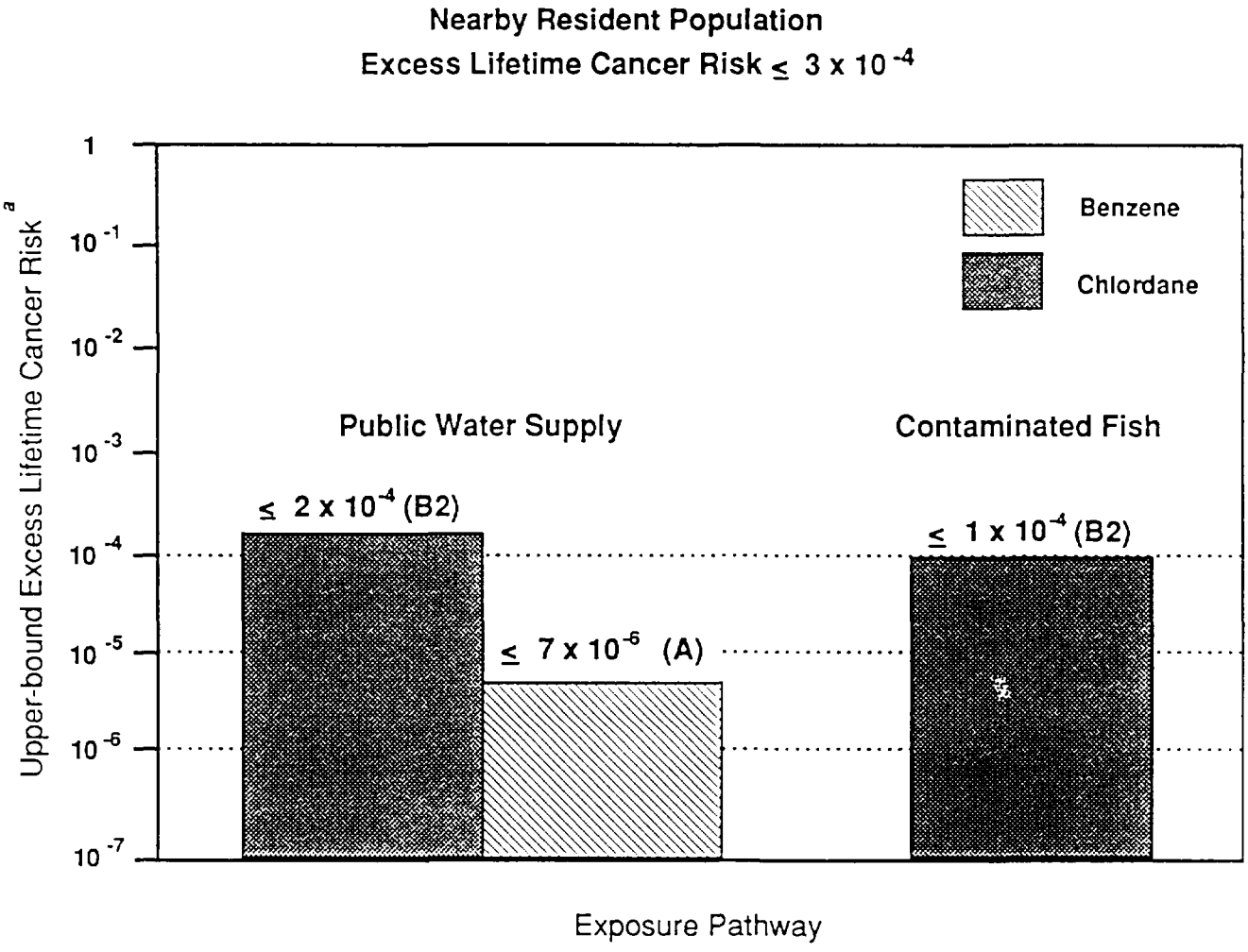
8.6.2 SUMMARIZE RISK INFORMATION IN TABLES

A tabular summary of the cancer risks and noncancer hazard indices should be prepared for all exposure pathways and land uses analyzed and for all substances carried through the risk assessment. These tables must be accompanied by explanatory text, as described in the previous section, and should not be allowed to stand alone as the entire risk characterization. The sample table formats presented in Chapter 6 and in Exhibits 8-2 to 8-6 provide basic summary formats. Exhibits 8-7 and 8-8 provide examples of optional presentations that might assist in visualization of the risk assessment results. These bar graphs present the baseline cancer risk estimates and noncancer hazard indices, respectively, by pathway for an identified subpopulation near the site. The stacked bars in Exhibit 8-8 allow the reader to immediately identify the pathway(s) contributing most to the total hazard index as well as identify the substances driving the indices in each pathway. Reference levels are also provided (e.g., hazard index of 1.0). Exhibits 8-5 and 8-6 introduced in Section 8.4.1 provide examples of figures that could help the RPM or other risk manager visualize the impact of various assumptions and uncertainties on the final risk or hazard index estimate. In addition, graphics relating risk level (or magnitude of hazard index) to concentrations of substances in environmental media and cost of "treatment" could allow the RPM or other risk manager to weigh the benefits of various remedial alternatives more easily. Examples of the last type of graphics are presented in Part C of this manual.

In a few succinct concluding paragraphs, summarize the results of the risk characterization step. It is the responsibility of the risk assessment team members, who are familiar with all steps in the site risk assessment, to highlight the major conclusions of the risk assessment. The discussion should summarize both the qualitative and the quantitative findings of cancer risks and noncancer hazards, and properly qualify these by mention of major assumptions and uncertainties in the assessment.

EXHIBIT 8-7

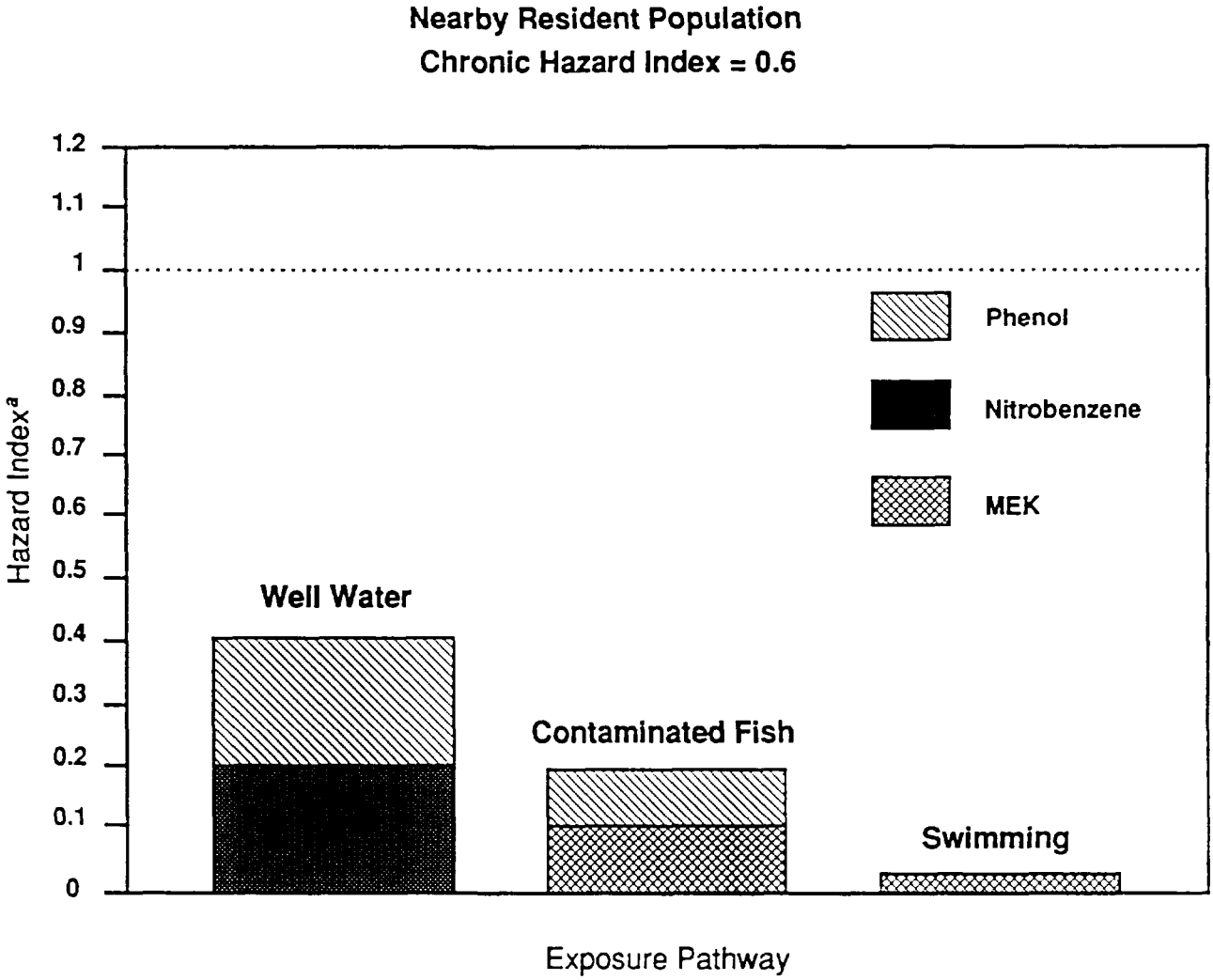
EXAMPLE OF PRESENTATION OF RELATIVE CONTRIBUTION OF INDIVIDUAL CHEMICALS TO EXPOSURE PATHWAY AND TOTAL CANCER RISK ESTIMATES



[a] The risk of developing cancer is plotted on a log scale. A risk of 10^{-4} indicates a probability of 1 chance in 10,000 of an individual developing cancer. Risks of 10^{-5} and 10^{-6} correspond to probabilities of 1 chance in 100,000 and 1 chance in 1,000,000, respectively. Values in parentheses represent EPA's weight-of-evidence classification of the agent as a potential human carcinogen: A = human carcinogen; and B2 = probable human carcinogen (with sufficient evidence in animals and inadequate or no evidence in humans).

EXHIBIT 8-8

EXAMPLE OF PRESENTATION OF RELATIVE CONTRIBUTION OF INDIVIDUAL CHEMICALS TO EXPOSURE PATHWAY AND TOTAL HAZARD INDEX ESTIMATES



[a] The hazard index is equal to the sum of the hazard quotients (i.e., exposure level/RfD) for each chemical. It is not a probability; a hazard index or quotient of ≤1.0 indicates that it is unlikely for even sensitive populations to experience adverse health effects.

ENDNOTE FOR CHAPTER 8

1. The probability of an individual developing cancer following exposure to more than one carcinogen is the probability of developing cancer from at least one of the carcinogens. For two carcinogens, the precise equation for estimating this probability is $risk_1 + risk_2 - probability\ (risk_1, risk_2)$ where the latter term is the joint probability of the two risks occurring in the same individual. If the risk to agent 1 is distributed in the population independently of the risk to agent 2, the latter term would equal $(risk_1)(risk_2)$. This equation can be expanded to evaluate risks from more than two substances.

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CHAPTER 9

DOCUMENTATION, REVIEW, AND MANAGEMENT TOOLS FOR THE RISK ASSESSOR, REVIEWER, AND MANAGER

This chapter provides tools for the documentation, review, and management of the baseline risk assessment. These tools will help ensure completeness and consistency throughout the risk assessment and in the reporting of assessment results. Section 9.1 provides documentation tools (for risk assessors), Section 9.2 provides review tools (for risk assessment reviewers), and Section 9.3 provides management tools (for remedial project managers [RPMs] and other decision-makers concerned with the site).

9.1 DOCUMENTATION TOOLS

Throughout Chapters 4 to 8 of this manual, guidance is provided to the risk assessor on how to summarize and document many beginning, intermediate, and final steps of the risk assessment. The purpose of this section is to consolidate that guidance, provide a final check to ensure that all appropriate documentation has been completed, and provide additional information that should be helpful. This section addresses (1) basic principles of documenting a Superfund site risk assessment (e.g., key "dos" and don'ts", the rationale for consistency), (2) a suggested outline and guidance for the risk assessment report, and (3) guidance for providing risk assessment summaries in other key reports.

9.1.1 BASIC PRINCIPLES

There are three basic principles for documenting a baseline risk assessment:

(1) address the main objectives of the risk assessment;

(2) communicate using clear, concise, and relevant text, graphics, and tables; and

(3) use a consistent format.

Addressing the objectives. The objectives of the baseline risk assessment -- to help determine whether additional response action is necessary at the site, to provide a basis for determining residual chemical levels that are adequately protective of public health, to provide a basis for comparing potential health impacts of various remedial alternatives, and to help support selection of the "no-action" remedial alternative (where appropriate) -- should be considered carefully during the documentation of the risk assessment. Recognizing these objectives early and presenting the results of the risk assessment with them in mind will assist the RPM and other decision-makers at the site with readily obtaining and using the necessary information to evaluate the objectives. Failing to recognize the importance of the objectives could result in a risk assessment report that appears misdirected and/or unnecessary.

Communicating. Clearly and concisely communicating the relevant results of the risk assessment can be one of the most important aspects of the entire RI/FS. If done correctly, a useful instrument for mitigating public health threats will have been developed. If done incorrectly, however, risks could be underemphasized, possibly leading to the

occurrence of adverse health effects, or they could be overemphasized, possibly leading to the unnecessary expenditure of limited resources. See the box below for some helpful hints on communicating the baseline risk assessment.

HELPFUL HINTS: COMMUNICATING THE BASELINE RISK ASSESSMENT

Try to:

- use a mix of well written text, illustrative graphics, and summary tables;
- explain the major steps and the results of the risk assessment in terms easily understood by the general public (and especially by members of exposed or potentially exposed populations);
- define highly technical terms early (e.g., in a glossary); and
- use a standard quantitative system – preferably the metric system – throughout and units that are the same where possible (e.g., ug/L for all water concentrations).

Avoid:

- the use of large blocks of text unbroken by any headings, graphics, tables, lists, or other "visual dividers";
- the presentation of much quantitative information within the text (rather than in tables); and
- the drawing of "risk management" conclusions (e.g., stating that the total or largest risk is insignificant).

Many skills for communicating the baseline risk assessment also can be learned by reviewing the literature on risk communication. The following box lists just some of the literature that is available. Courses on the subject also exist.

RISK COMMUNICATION GUIDANCE

Explaining Environmental Risk (EPA 1986)

Tools for Environmental Professionals Involved in Risk Communication At Hazardous Waste Facilities Undergoing Siting, Permitting, or Remediation (Bean 1987)

Improving Dialogue with Communities: A Short Guide for Government Risk Communication (NJDEP 1987)

Seven Cardinal Rules of Risk Communication (EPA 1988a)

Using a consistent format. A consistent format for all Superfund risk assessments is strongly recommended for four important reasons:

(1) it encourages consistency and completeness in the assessment itself;

(2) it allows for easier review of the risk assessments;

(3) it encourages consistent use of the results by RPMs and other decision-makers; and

(4) it helps demonstrate to the public and others that risk assessments are conducted using the same framework (if not the same specific procedures).

Using other formats can lead to slower review times, different interpretations of similar results, and the charge that risk assessments are inappropriately being conducted differently from one site to another. The following subsections provide guidance on the use of consistent formats.

9.1.2 BASELINE RISK ASSESSMENT REPORT

The baseline risk assessment report references and supports the RI/FS report. Depending on the site, the risk assessment report can range from a small, simple document with no appendices that can simply be added to the RI/FS report as a chapter, to a large, complex document with many appendices that can "stand alone." This subsection provides general guidance on how to organize the baseline risk assessment report and which information should be included in the report. More detailed guidance, however, is found by following the guidance in previous chapters of this

manual. Careful use of that guidance will ensure a well-documented baseline risk assessment report.

Exhibit 9-1 provides a suggested outline for the full baseline risk assessment report. This outline generally follows the flow of the risk assessment and the organization of this manual. The "bulleted" items are not necessarily section headings, but rather are often items that should be considered when writing the report. Note that, as with the manual, not all components of the outline are applicable to all sites. This is especially true if the risk assessment report will be a chapter in the RI/FS report. At some sites, and especially when the risk assessment report will be a stand-alone document, more site-specific items could be added to the report.

Examples of tables and graphics that should be included in the report are presented as exhibits in previous chapters of this manual. Note, however, that additional tables and graphics may be useful.

This suggested outline may be used as a review guide by risk assessors (and risk assessment reviewers) to ensure that all appropriate components of the assessment have been addressed. Section 9.2 addresses review tools in greater detail.

9.1.3 OTHER KEY REPORTS

Two important reports that must include summaries of the baseline risk assessment are (1) the remedial investigation/feasibility study (RI/FS) report and (2) the record of decision (ROD) report.

Summary for the RI/FS report. One of the chapters of the RI/FS typically is devoted to a summary of the baseline risk assessment. Part of this summary should address the human health evaluation (the other part should address the environmental evaluation). The human health summary should follow the same outline as the full baseline risk assessment report, with almost each section of the summary being a distillation of each full report chapter. The risk characterization chapter is an exception, however, in that it could be included in the RI/FS report essentially unchanged. Most tables and graphics should be included unchanged as well. For more information, see *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA 1988b).

Summary for the ROD report. The ROD documents the remedial action selected for a site. It consists of three basic components: (1) a Declaration; (2) a Decision Summary; and (3) a Responsiveness Summary. The second component, a Decision Summary, provides an overview of the site-specific factors and analyses that led to the selection of the remedy. Included in this component is a summary of site risks. As with the risk assessment summary for the RI/FS report, the summary for the ROD report should follow the same outline as the full risk assessment. This summary, however, should be much more abbreviated than the RI/FS summary, although care must be taken to address all of the relevant site-specific results. For more information, see *Interim Final Guidance on Preparing Superfund Decision Documents: The Proposed Plan, the Record of Decision, Explanation of Significant Differences, and the Record of Decision Amendment* (EPA 1989).

9.2 REVIEW TOOLS

This section provides guidelines on reviewing a risk assessment report. A checklist of many essential criteria that should be adequately addressed in any good risk assessment is provided (Exhibit 9-2). The checklist touches upon issues that are often problematic and lead to difficulty and delay in the review of risk assessments. Principal questions are presented in the checklist with qualifying statements or follow-up questions, as well as references to appropriate chapters and sections of this manual. The checklist is intended as a guide to assist the preliminary reviewer by ensuring that critical issues concerning the quality and adequacy of information are not overlooked at the screening level review of risk assessments. Experience has shown that reviewers should pay particular attention to the following concerns.

- Were all appropriate media sampled?
- Were any site-related chemicals (e.g., human carcinogens) eliminated from analysis without appropriate justification?

EXHIBIT 9-1

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

1.0 INTRODUCTION

1.1 Overview
- General problem at site
- Site-specific objectives of risk assessment

1.2 Site Background
- Site description
- Map of site
- General history
  - -- Ownership
  - -- Operations
  - -- Contamination
- Significant site reference points
- Geographic location relative to offsite areas of interest
- General sampling locations and media

1.3 Scope of Risk Assessment
- Complexity of assessment and rationale
- Overview of study design

1.4 Organization of Risk Assessment Report

2.0 IDENTIFICATION OF CHEMICALS OF POTENTIAL CONCERN

2.1 General Site-specific Data Collection Considerations
- Detailed historical information relevant to data collection
- Preliminary identification of potential human exposure
- Modeling parameter needs
- Background sampling
- Sampling locations and media
- Sampling methods
- QA/QC methods
- Special analytical services (SAS)

2.2 General Site-specific Data Evaluation Considerations
- Steps used (including optional screening procedure steps, if used)
- QA/QC methods during evaluation
- General data uncertainty

2.3 Environmental Area or Operable Unit 1 (Complete for All Media)
- Area- and media-specific sample collection strategy (e.g., sample size, sampling locations)
- Data from site investigations

(continued)

EXHIBIT 9-1 (continued)

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

- Evaluation of analytical methods
- Evaluation of quantitation limits
- Evaluation of qualified and coded data
- Chemicals in blanks
- Tentatively identified compounds
- Comparison of chemical concentrations with background
- Further limitation of number of chemicals
- Uncertainties, limitations, gaps in quality of collection or analysis

2.4 Environmental Area or Operable Unit 2 (Repeat for All Areas or Operable Units, As Appropriate)

2.X Summary of Chemicals of Potential Concern

3.0 EXPOSURE ASSESSMENT

3.1 Characterization of Exposure Setting
- Physical Setting
  - -- Climate
  - -- Vegetation
  - -- Soil type
  - -- Surface hydrology
  - -- Ground-water hydrology
- Potentially Exposed Populations
  - -- Relative locations of populations with respect to site
  - -- Current land use
  - -- Potential alternate future land uses
  - -- Subpopulations of potential concern

3.2 Identification of Exposure Pathways
- Sources and receiving media
- Fate and transport in release media
- Exposure points and exposure routes
- Integration of sources, releases, fate and transport mechanisms, exposure points, and exposure routes into complete exposure pathways
- Summary of exposure pathways to be quantified in this assessment

3.3 Quantification of Exposure
- Exposure concentrations
- Estimation of chemical intakes for individual pathways

(continued)

EXHIBIT 9-1 (continued)

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

3.4 Identification of Uncertainties
- Current and future land-use
- Environmental sampling and analysis
- Exposure pathways evaluated
- Fate and transport modeling
- Parameter values

3.5 Summary of Exposure Assessment

4.0 TOXICITY ASSESSMENT

4.1 Toxicity Information for Noncarcinogenic Effects
- Appropriate exposure periods for toxicity values
- Up-to-date RfDs for all chemicals
- One- and ten-day health advisories for shorter-term oral exposures
- Overall data base and the critical study on which the toxicity value is based (including the critical effect and the uncertainty and modifying factors used in the calculation)
- Effects that may appear at doses higher than those required to elicit the critical effect
- Absorption efficiency considered

4.2 Toxicity Information for Carcinogenic Effects
- Exposure averaged over a lifetime
- Up-to-date slope factors for all carcinogens
- Weight-of-evidence classification for all carcinogens
- Type of cancer for Class A carcinogens
- Concentration above which the dose-response curve is no longer linear

4.3 Chemicals for Which No EPA Toxicity Values Are Available
- Review by ECAO
- Qualitative evaluation
- Documentation/justification of any new toxicity values developed

4.4 Uncertainties Related to Toxicity Information
- Quality of the individual studies
- Completeness of the overall data base

4.5 Summary of Toxicity Information

5.0 RISK CHARACTERIZATION

5.1 Current Land-use Conditions
- Carcinogenic risk of individual substances
- Chronic hazard quotient calculation (individual substances)
- Subchronic hazard quotient calculation (individual substances)

(continued)

EXHIBIT 9-1 (continued)

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

- Shorter-term hazard quotient calculation (individual substances)
- Carcinogenic risk (multiple substances)
- Chronic hazard index (multiple substances)
- Subchronic hazard index (multiple substances)
- Shorter-term hazard index calculation (multiple substances)
- Segregation of hazard indices
- *Justification for combining risks across pathways*
- Noncarcinogenic hazard index (multiple pathways)
- Carcinogenic risk (multiple pathways)

5.2 Future Land-use Conditions
- Carcinogenic risk of individual substances
- Chronic hazard quotient calculation (individual substances)
- Subchronic hazard quotient calculation (individual substances)
- Carcinogenic risk (multiple substances)
- Chronic hazard index (multiple substances)
- Subchronic hazard index (multiple substances)
- Segregation of hazard indices
- Justification for combining risks across pathways
- Noncarcinogenic hazard index (multiple pathways)
- Carcinogenic risk (multiple pathways)

5.3 Uncertainties
- Site-specific uncertainty factors
  - -- Definition of physical setting
  - -- Model applicability and assumptions
  - -- Parameter values for fate/transport and exposure calculations
- Summary of toxicity assessment uncertainty
  - -- Identification of potential health effects
  - -- Derivation of toxicity value
  - -- Potential for synergistic or antagonistic interactions
  - -- Uncertainty in evaluating less-than-lifetime exposures

5.4 Comparison of Risk Characterization Results to Human Studies
- ATSDR health assessment
- Site-specific health studies (pilot studies or epidemiological studies)
- Incorporation of studies into the overall risk characterization

5.5 Summary Discussion and Tabulation of the Risk Characterization
- Key site-related contaminants and key exposure pathways identified
- Types of health risk of concern
- Level of confidence in the quantitative information used to estimate risk
- Presentation of qualitative information on toxicity

(continued)

EXHIBIT 9-1 (continued)

SUGGESTED OUTLINE FOR A BASELINE RISK ASSESSMENT REPORT

- Confidence in the key exposure estimates for the key exposure pathways
- Magnitude of the carcinogenic and noncarcinogenic risk estimates
- Major factors driving risk
- Major factors contributing to uncertainty
- Exposed population characteristics
- Comparison with site-specific health studies

6.0 SUMMARY

6.1 Chemicals of Potential Concern
6.2 Exposure Assessment
6.3 Toxicity Assessment
6.4 Risk Characterization

EXHIBIT 9-2

REVIEWER CHECKLIST

1.0 GENERAL CONCERNS

- Were the site-specific objective(s) of the risk assessment stated? (HHEM - 1)
- Was the scope of the assessment described (e.g., in terms of the complexity of the assessment and rationale, data needs, and overview of the study design)? (HHEM - 1.1.1, 3.5)
- Was an adequate history of site activities provided, including a chronology of land use (e.g., specifying agriculture, industry, recreation, waste deposition, and residential development at the site)? (HHEM - 2.1.4, 9.1)
- Was an initial qualitative overview of the nature of contamination included (e.g., specifying in a general manner the kinds of contaminants, media potentially contaminated)? (HHEM - 2.1.4, 9.1)
- Was a general map of the site depicting boundaries and surface topography included, which illustrates site features, such as fences, ponds, structures, as well as geographical relationships between specific potential receptors and the site? (HHEM - 2.1.4, 9.1)

2.0 CONCERNS IN REVIEWING DATA COLLECTION AND EVALUATION

2.1 Data Collection

- Was an adequate "conceptual model" of the site discussed? (HHEM - 4.2)
  - -- a qualitative discussion of potential or suspected sources of contamination, types and concentrations of contaminants detected at the site, potentially contaminated media, as well as potential exposure pathways and receptors
- Was an adequate Data Quality Objectives (DQO) statement provided? (HHEM - 4.1.4)
  - -- a statement specifying both the qualitative and quantitative nature of the sampling data, in terms of relative quality and intent for use, issued prior to data collection, which helps to ensure that the data collected will be appropriate for the intended objectives of the study
- Were key site characteristics documented? (HHEM - 4.3, 4.5)
  - -- soil/sediment parameters (e.g., particle size, redox potential, mineral class, organic carbon and clay content, bulk density, and porosity)
  - -- hydrogeological parameters (e.g., hydraulic gradient; pH/Eh, hydraulic conductivity, location, saturated thickness, direction, and rate of flow of aquifers, relative location of bedrock layer)

(continued)

EXHIBIT 9-2 (continued)

REVIEWER CHECKLIST

-- hydrological parameters (e.g., hardness, pH, dissolved oxygen, salinity, temperature, total suspended solids, flow rates, and depths of rivers or streams; estuary and embayment parameters such as tidal cycle, range, and area; as well as lake parameters such as area, volume, depth, and depth to thermocline)

-- meteorological parameters (e.g., direction of prevailing wind, average wind speed, temperature, humidity, annual average and 24 hour maximum rainfall)

- Were all appropriate media sampled? (HHEM - 4.4, 4.5, 4.6)

  -- was there adequate justification for any omissions?

  -- were literature estimates employed for omissions in background sampling and were they referenced properly?

- Were all key areas sampled, based on all available information (e.g., preliminary assessment, field screening)? (HHEM - 4.4, 4.5, 4.6)

- Did sampling include media along potential routes of migration (e.g., between the contaminant source and potential future exposure points)? (HHEM - 4.5, 4.6)

- Were sampling locations consistent with nature of contamination (e.g., at the appropriate depth)? (HHEM - 4.5, 4.6)

- Were sampling efforts consistent with field screening and visual observations in locating "hot spots"? (HHEM - 4.5, 4.6)

- Were detailed sampling maps provided, indicating the location, type (e.g., grab, composite, duplicate), and numerical code of each sample? (HHEM - 5.10)

- Did sampling include appropriate QA/QC measures (e.g., replicates, split samples, trip and field blanks)? (HHEM - 4.7, 5.4)

- Were background samples collected from appropriate areas (e.g., areas proximate to the site, free of potential contamination by site chemicals or anthropogenic sources, and similar to the site in topography, geology, meteorology, and other physical characteristics)? (HHEM - 4.4, 5.7)

2.2 Data Evaluation

- Were any site-related chemicals (e.g., human carcinogens) eliminated from analysis without appropriate justification? (HHEM - 5.9)

(continued)

EXHIBIT 9-2 (continued)

REVIEWER CHECKLIST

-- as infrequently detected chemicals (HHEM - 5.3.3, 5.9.3)

-- as non-detects in a specific medium without employing a "proxy" concentration (HHEM - 5.3)

-- as common laboratory contaminants even though sample concentrations were significantly higher than that found in blanks? (HHEM - 5.5)

-- as present at a "ubiquitous level"? (HHEM - 5.7)

- Were inappropriate "proxy concentrations" assigned to site-related chemicals? (HHEM - 5.3)

  -- was a value of zero or the instrument detection limit (IDL) assigned?

  -- was an erroneous sample-specific quantitation limit employed?

- Were appropriate analytical methods employed for collection of data upon which risk estimates are based? (HHEM - 5.2)

  -- were the methods consistent with the requisite level of sensitivity?

  -- were established procedures with adequate QA/QC measures employed?

- Did the data meet the Data Quality Objectives (DQO)? (HHEM - 4.1.4)

  -- were the sampling methods consistent with the intended uses of data?

- Were appropriate data qualifiers employed? (HHEM - 5.4)

- Were special analytical services (SAS) employed when appropriate? (HHEM - 5.3)

  -- was SAS employed as an adjunct to routine analysis in cases where certain contaminants were suspected at low levels, as non-TCL chemicals, in non-standard matrices, or in situations requiring a quick turnaround time?

3.0 CONCERNS IN REVIEWING THE EXPOSURE ASSESSMENT

- Were "reasonable maximum exposures" considered (i.e., the highest exposures that are reasonably expected to occur)? (HHEM - 6.1.2, 6.4.1, 6.6)

- Were current and future land uses considered? (HHEM - 6.1.2, 6.2)

(continued)

EXHIBIT 9-2 (continued)

REVIEWER CHECKLIST

- Was residential land use considered as an alternative future land use? (HHEM - 6.2.2)

  -- if not, was a valid rationale provided?

- Were all potential sensitive subpopulations considered (e.g., elderly people, pregnant or nursing women, infants and children, and people with chronic illnesses)? (HHEM - 6.2.2)

- Were all significant contaminant sources considered? (HHEM - 6.3.1)

- Were all potential contaminant release mechanisms considered, such as volatilization, fugitive dust emission, surface runoff/overland flow, leaching to ground water, tracking by humans/animals, and soil gas generation? (HHEM - 6.3.1)

- Were all potential contaminant transport pathways considered, such as direct air transport downwind, diffusion in surface water, surface water flow, ground-water flow, and soil gas migration? (HHEM - 6.3)

- Were all relevant cross-media transfer effects considered, such as volatilization to air, wet deposition, dry deposition, ground-water discharge to surface, and ground-water recharge from surface water? (HHEM - 6.3)

- Were all media potentially associated with exposure considered? (HHEM - 6.2, 6.3)

- Were all relevant site-specific characteristics considered, including topographical, hydrogeological, hydrological, and meteorological parameters? (HHEM - 6.1, 6.3)

- Were all possible exposure pathways considered? (HHEM - 6.3)

  -- was a valid rationale offered for exclusion of any potential pathways from quantitative evaluation?

- Were all "spatial relationships" adequately considered as factors that could affect the level of exposure (e.g., hot spots in an area that is frequented by children, exposure to ground water from two aquifers that are not hydraulically connected and that differ in the type and extent of contamination)? (HHEM - 6.2, 6.3)

- Were appropriate approaches employed for calculating average exposure concentrations? (HHEM - 6.4, 6.5)

  -- was a valid rationale provided for using geometric or arithmetic means?

- Were appropriate or standard default values used in exposure calculations (e.g., age-specific body weights, appropriate exposure frequency and duration values)? (HHEM - 6.4, 6.5, 6.6)

(continued)

EXHIBIT 9-2 (continued)

REVIEWER CHECKLIST

4.0 CONCERNS IN REVIEWING THE TOXICITY ASSESSMENT

- Was the exclusion of any carcinogen from analysis adequately justified (e.g., were "weight-of-evidence" classifications and completeness of exposure pathways considered in this decision)? (HHEM - 5.9, 7.3)

- Were appropriate "route-to-route" extrapolations performed in cases where a toxicity value was applied across differing routes of exposure? (HHEM - 7.5.1, 8.1.2)

  -- were the extrapolations based on appropriate guidance?

- Were appropriate toxicity values employed based on the nature of exposure? (HHEM - 7.4, 7.5)

  -- were subchronic vs. chronic RfDs applied correctly based on the duration of exposure?

  -- were all sensitive subpopulations, such as pregnant or nursing women potentially requiring developmental RfDs (RfD_ds), considered in the selection of the toxicity values used?

- Were the toxicity values that were used consistent with the values contained within the Integrated Risk Information System (IRIS) or other EPA documents? (HHEM - 7.4, 7.5)

5.0 CONCERNS IN REVIEWING THE RISK CHARACTERIZATION

- Were exposure estimates and toxicity values consistently expressed as either intakes or absorbed doses for each chemical taken through risk characterization? (HHEM - 8.1.2)

  -- was a valid rationale given for employing values based on absorbed dose?

- Were all site-related chemicals that were analyzed in the exposure assessment considered in risk characterization? (HHEM - 8.1.2)

  -- were inconsistencies explained?

- Were risks appropriately summed only across exposure pathways that affect the same individual or population subgroup, and in which the same individual or population subgroup faces the "reasonable maximum exposure," based on the assumptions employed in the exposure assessment? (HHEM - 8.3)

- Were sources of uncertainty adequately characterized? (HHEM - 8.4)

- Were current and future land uses considered?
- Were all significant contaminant sources considered?
- Were appropriate or standard default values used in exposure calculations?
- Were the toxicity values that were used consistent with the values contained within the Integrated Risk Information System (IRIS) or other EPA documents?

Although the checklist addresses many pertinent issues, it is not a complete listing of all potential concerns, since this objective is beyond the scope of a preliminary review tool. In addition, some of the concerns listed are not necessarily appropriate for all risk assessment reports.

The recommended steps in reviewing a risk assessment report are as follows:

(1) compare the risk assessment report outline to the suggested outline in Section 9.1 of this chapter (i.e., Exhibit 9-1);

(2) use the checklist in this section (i.e., Exhibit 9-2); and

(3) conduct a comprehensive review.

The outline (Exhibit 9-1) and the checklist (Exhibit 9-2) are intended only as tools to assist in a preliminary review of a risk assessment, and are not designed to replace the good judgment needed during the comprehensive review. These two tools should provide a framework, however, for the timely screening of risk assessments by reviewers with a moderate level of experience in the area. If these steps are followed in order, then some of the major problems with a risk assessment report (if any) can be identified before significant resources are expended during the comprehensive review.

9.3 MANAGEMENT TOOLS

This section provides a concise checklist for the RPM to use in carrying out their role in the risk assessment process (see Exhibit 9-3). Other decision-makers at the site also may find this checklist useful. Specific points at which the managers should be involved, or may be called upon to become involved, during the risk assessment are discussed in Chapters 4 through 8 of the manual. This checklist extracts information from those chapters, and also includes pointers on planning and involvement for the manager. The purpose of the checklist is to involve managers in the direction and development of the risk assessment and thereby avoid serious mistakes or costly misdirections in focus or level of effort.

Although the checklist is shaped to suggest when and how the manager should become involved in the risk assessment process, it is assumed that part of the manager's involvement will require consultation with technical resources available in the region or state. The checklist advises consulting the "regional risk assessment support staff" at a number of points in the process. This contact may not be one person, but could be a number of different technical people in the region, such as a toxicologist, hydrogeologist, or other technical reviewer. The manager should become aware of the resources available to him or her, and use them when appropriate to ensure that the risk assessment developed is useful and accurate.

EXHIBIT 9-3

CHECKLIST FOR MANAGER INVOLVEMENT

1. GETTING ORGANIZED

   - Ensure that the workplan for the risk assessment contractor support is in place (if needed).
   - Identify EPA risk assessment support personnel (to be used throughout the risk assessment process).
   - Gather relevant information, such as appropriate risk assessment guidances and site-specific data and reports.
   - Identify available state, county, and other non-EPA resources.

2. BEFORE THE SCOPING MEETING

   - Make initial contact with risk assessor.
   - Provide risk assessor with available guidances and site data.
   - Determine (or review) data collection needs for risk assessment, considering:
     -- modeling parameter needs;
     -- type and location of background samples;
     -- the preliminary identification of potential human exposure;
     -- strategies for sample collection appropriate to site/risk assessment data needs;
     -- statistical methods;
     -- QA/QC measures of particular importance to risk assessment;
     -- special analytical services (SAS) needs;
     -- alternate future land use; and
     -- location(s) in ground water that will be used to evaluate future ground-water exposures.

3. AT THE SCOPING MEETING

   - Present risk assessment data collection needs.
   - Ensure that the risk assessment data collection needs will be considered in development of the sampling and analysis plan.
   - Where limited resources require that less-than-optimal sampling be conducted, discuss potential impacts on risk assessment results.

4. AFTER THE SCOPING MEETING

   - Ensure that the risk assessor reviews and approves the sampling and analysis plan.
   - Consult with ATSDR if human monitoring is planned.

(continued)

EXHIBIT 9-3 (continued)

CHECKLIST FOR MANAGER INVOLVEMENT

5. DURING SAMPLING AND ANALYSIS

- Ensure that risk assessment needs are being met during sampling.
- Provide risk assessor with any preliminary sampling results so that he/she can determine if sampling should be refocused.
- Consult with ATSDR to obtain a status report on any human monitoring that is being conducted. Provide any results to risk assessor.

6. DURING DEVELOPMENT OF RISK ASSESSMENT

- Meet with risk assessor to discuss basis of excluding chemicals from the risk assessment (and developing the list of chemicals of potential concern). Confirm appropriateness of excluding chemicals.
- Confirm determination of alternate future land use.
- Confirm location(s) in ground water that will be used to evaluate future ground-water exposures.
- Understand basis for selection of pathways and potentially exposed populations.
- Facilitate discussions between risk assessor and EPA risk assessment support personnel on the following points:
  - -- the need for any major exposure, fate, and transport models (e.g., air or ground-water dispersion models) used;
  - -- site-specific exposure assumptions;
  - -- non-EPA-derived toxicity values; and
  - -- appropriate level of detail for uncertainty analysis, and the degree to which uncertainties will be quantified.
- Discuss and approve combination of pathway risks and hazard indices.
- Ensure that end results of risk characterization have been compared with ATSDR health assessments and other site-specific human studies that might be available.

7. REVIEWING THE RISK ASSESSMENT

- Allow sufficient time for review and incorporation of comments.
- Ensure that reviewers' comments are incorporated.

(continued)

EXHIBIT 9-3 (continued)

CHECKLIST FOR MANAGER INVOLVEMENT

8. COMMUNICATING THE RISK ASSESSMENT

- Plan a briefing among technical staff to discuss significant findings and uncertainties.
- Discuss development of graphics, tools, and presentations to assist risk management decisions.
- Consult with other groups (e.g., community relations staff), as appropriate.
- Brief upper management.

REFERENCES FOR CHAPTER 9

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CHAPTER 10

RADIATION RISK ASSESSMENT GUIDANCE

There are many sites contaminated with radioactive substances that are included on the National Priorities List (NPL), and additional sites are expected in future NPL updates. This chapter provides supplemental baseline risk assessment guidance for use at these sites. This guidance is intended as an overview of key differences in chemical and radionuclide assessments, and not as a comprehensive, stand-alone approach for assessing the risks posed by radiation.

The reader should be familiar with the guidance provided in Chapters 2 through 9 before proceeding further in Chapter 10. Although the discussions in the previous chapters focus primarily on chemically contaminated sites, much of the information presented is also applicable to the evaluation of radioactively contaminated Superfund sites. For consistency and completeness, the topics discussed in each section of this chapter parallel the topics covered in each of the previous chapters.

After a brief introduction to some of the basic principles and concepts of radiation protection (Section 10.1), seven additional areas are addressed:

(1) Regulation of Radioactively Contaminated Sites (Section 10.2);

(2) Data Collection (Section 10.3);

(3) Data Evaluation (Section 10.4);

(4) Exposure and Dose Assessment (Section 10.5);

ACRONYMS, SYMBOLS, AND UNITS FOR CHAPTER 10

A(t) = Activity at Time t
Bq = Becquerel
Ci = Curie
CLP = Contract Laboratory Program
D = Absorbed Dose
DCF = Dose Conversion Factor Per Unit Intake
H_E = Effective Dose Equivalent
H_T = Dose Equivalent Averaged Over Tissue or Organ T
$H_{E,50}$ = Committed Effective Dose Equivalent Per Unit Intake
$H_{T,50}$ = Committed Dose Equivalent Averaged Over Tissue T
LET = Linear Energy Transfer
LLD = Lower Limit of Detection
MeV = Million Electron Volts
N = Modifying Factor in the Definition of Dose Equivalent
pCi = PicoCurie (10^{-12} Ci)
Q = Quality Factor in Definition of Dose Equivalent
RBE = Relative Biological Effectiveness
SI = International System of Units
Sv = Sievert
T = Tissue or Target Organs
w_T = Weighting Factor in the Definition of Effective Dose Equivalent and Committed Effective Dose Equivalent

(5) Toxicity Assessment (Section 10.6);

(6) Risk Characterization (Section 10.7); and

(7) Documentation, Review, and Management Tools for the Risk Assessor, Reviewer, and Manager (Section 10.8).

DEFINITIONS FOR CHAPTER 10

Absorbed Dose (D). The mean energy imparted by ionizing radiation to matter per unit mass. The special SI unit of absorbed dose is the gray (Gy); the conventional unit is the rad (1 rad = 0.01 Gy).

Becquerel (Bq). One nuclear disintegration per second; the name for the SI unit of activity. 1 Bq = 2.7×10^{-11} Ci.

Committed Dose Equivalent ($H_{T,50}$). The total dose equivalent (averaged over tissue T) deposited over the 50-year period following the intake of a radionuclide.

Committed Effective Dose Equivalent ($H_{E,50}$). The weighted sum of committed dose equivalents to specified organs and tissues, in analogy to the effective dose equivalent.

Curie (Ci). 3.7×10^{10} nuclear disintegrations per second, the name for the conventional unit of activity. 1 Ci = 3.7×10^{10}Bq.

Decay Product(s). A radionuclide or a series of radionuclides formed by the nuclear transformation of another radionuclide which, in this context, is referred to as the parent.

Dose Conversion Factor (DCF). The dose equivalent per unit intake of radionuclide.

Dose Equivalent (H). The product of the absorbed dose (D), the quality factor (Q), and any other modifying factors (N). The SI unit of dose equivalent is the sievert (Sv); the conventional unit is the rem (1 rem = 0.01 Sv).

Effective Dose Equivalent (H_E). The sum over specified tissues of the products of the dose equivalent in a tissue or organ (T) and the weighting factor for that tissue.

External Radiation. Radiations incident upon the body from an external source.

Gray (Gy). The SI unit of absorbed dose. 1Gy = 1 Joule kg^{-1} = 100 rad.

Half-Life (physical, biological, or effective). The time for a quantity of radionuclide, i.e., its activity, to diminish by a factor of a half (because of nuclear decay events, biological elimination of the material, or both.).

Internal Radiation. Radiation emitted from radionuclides distributed within the body.

Ionizing Radiation. Any radiation capable of displacing electrons from atoms or molecules, thereby producing ions.

Linear Energy Transfer (LET). A measure of the rate of energy absorption, defined as the average energy imparted to the absorbing medium by a charged particle per unit distance (KeV per um).

Nuclear Transformation. The spontaneous transformation of one radionuclide into a different nuclide or into a different energy state of the same nuclide.

Quality Factor (Q). The principal modifying factor that is employed in deriving dose equivalent, H, from absorbed dose, D; chosen to account for the relative biological effectiveness (RBE) of the radiation in question, but to be independent of the tissue or organ under consideration, and of the biological endpoint. For radiation protection purposes, the quality factor is determined by the linear energy transfer (LET) of the radiation.

Rad. The conventional unit for absorbed dose of ionizing radiation; the corresponding SI unit is the gray (Gy); 1 rad = 0.01 Gy = 0.01 Joule/kg.

Rem. An acronym of radiation equivalent man, the conventional unit of dose equivalent; the corresponding SI unit is the Sievert; 1 Sv = 100 rem.

Sievert (Sv). The special name for the SI unit of dose equivalent. 1 Sv = 100 rem.

Slope Factor. The age-averaged lifetime excess cancer incidence rate per unit intake (or unit exposure for external exposure pathways) of a radionuclide.

Weighting Factor (w_T). Factor indicating the relative risk of cancer induction or hereditary defects from irradiation of a given tissue or organ; used in calculation of effective dose equivalent and committed effective dose equivalent.

There are special hazards associated with handling radioactive waste and EPA strongly recommends that a health physicist experienced in radiation measurement and protection be consulted prior to initiating any activities at a site suspected of being contaminated with radioactive substances. EPA also recommends that the remedial project manager (RPM) or on-scene coordinator (OSC) should designate both a chemical risk assessor and a radiation risk assessor. These individuals should work closely with each other and the RPM to coordinate remedial activities (e.g., site scoping, health and safety planning, sampling and analysis) and exchange information common to both chemical and radionuclide assessments, including data on the physical characteristics of the site, potentially impacted populations, pathways of concern, and fate and transport models used. At the conclusion of the remedial investigation/feasibility study (RI/FS) process, the RPM should issue a single report that summarizes and integrates the results from both the chemical and the radiation risk assessments.

A two-phase evaluation is described for the radiation risk assessment. As discussed in Section 10.5, procedures established by the International Commission on Radiological Protection (ICRP 1979) and adopted by EPA in *Federal Guidance Report No. 11* (EPA 1988) are used to estimate the radiation dose equivalent to humans from potential exposures to radionuclides through all pertinent exposure pathways at a site. Those estimates of dose equivalent may be used for comparison with established radiation protection standards and criteria. However, this methodology was developed for regulation of occupational radiation exposures for adults and is not completely applicable for estimating health risk to the general population at a Superfund site. Therefore, a separate methodology is presented in Section 10.7.2 for estimating health risk, based on the age-averaged lifetime excess cancer incidence per unit intake (and per unit external exposure) for radionuclides of concern. Radiation risk assessments for Superfund sites should include estimates of both the dose equivalent computed as described in Section 10.5, and the health risk attributable to radionuclide exposures computed using the approach described in Section 10.7.

Only summary-level information is presented in this chapter, and references are provided to a number of supporting technical documents for further information. In particular, the reader is encouraged to consult Volume 1 of the *Background Information Document for the Draft Environmental Impact Statement for Proposed NESHAPS for Radionuclides* (EPA 1989a) for a more comprehensive discussion of EPA's current risk assessment methodology for radionuclides.

For additional radiation risk assessment information and guidance, RPMs and other interested individuals can contact the Office of Radiation Programs (ORP) within EPA headquarters at 202-475-9630 (FTS 475-9630). Interested individuals also can contact the Regional Radiation Program Managers within each of the EPA regional offices for guidance and health physics support.

10.1 RADIATION PROTECTION PRINCIPLES AND CONCEPTS

Radioactive atoms undergo spontaneous nuclear transformations and release excess energy in the form of ionizing radiation. Such transformations are referred to as radioactive decay. As a result of the radioactive decay process, one element is transformed into another; the newly formed element, called a decay product, will possess physical and chemical properties different from those of its parent, and may also be radioactive. A radioactive species of a particular element is referred to as a radionuclide or radioisotope. The exact mode of radioactive transformation for a particular radionuclide depends solely upon its nuclear characteristics, and is independent of the nuclide's chemical characteristics or physical state. A fundamental and unique characteristic of each radionuclide is its radioactive half-life, defined as the time required for one half of the atoms in a given quantity of the radionuclide to decay. Over 1,600 different radionuclides have been identified to date, with half-lives ranging from fractions of a second to millions of years. Selected radionuclides

of potential importance at Superfund sites are listed in Exhibit 10-1.

Radiation emitted by radioactive substances can transfer sufficient localized energy to atoms to remove electrons from the electric field of their nucleus (ionization). In living tissue this energy transfer can destroy cellular constituents and produce electrically charged molecules (i.e., free radicals). Extensive biological damage can lead to adverse health effects. The type of ionizing radiation emitted by a particular radionuclide depends upon the exact nature of the nuclear transformation, and may include emission of alpha particles, electrons (beta particles or positrons), and neutrons; each of these transformations may be accompanied by emission of photons (gamma radiation or x-rays). Each type of radiation differs in its physical characteristics and in its ability to inflict damage to biological tissue. These characteristics and effects are summarized in the box on this page.

Quantities of radionuclides are typically expressed in terms of activity at a given time t (A(t)). The SI unit of activity is the becquerel (Bq), which is defined as the quantity of a given radionuclide in which one atom is transformed per second (i.e., one decay per second). The conventional unit of activity is the curie (Ci), which is defined as the quantity of a given radionuclide in which 3.7×10^{10} atoms undergo nuclear transformation each second; one curie is approximately equivalent to the decay rate of one gram of Ra-226. A more convenient unit of activity for expressing environmental concentrations of radionuclides is the picoCurie (pCi), which is equal to 10^{-12} Ci. Occasionally, activity is expressed incorrectly in terms of counts per second (cps) or counts per minute (cpm): these refer to the number of transformations per unit time measured by a particular radiation detector and do not represent the true decay rate of the radionuclide. To derive activity values, count rate measurements are multiplied by radioisotope-specific detector calibration factors.

PRINCIPAL TYPES OF IONIZING RADIATION

Alpha particles are doubly charged cations, composed of two protons and two neutrons, which are ejected monoenergetically from the nucleus of an atom when the neutron to proton ratio is too low. Because of their relatively large mass and charge, alpha particles tend to ionize nearby atoms quite readily, expending their energy in short distances. Alpha particles will usually not penetrate an ordinary sheet of paper or the outer layer of skin. Consequently, alpha particles represent a significant hazard only when taken into the body, where their energy is completely absorbed by small volumes of tissues.

Beta particles are electrons ejected at high speeds from the nucleus of an unstable atom when a neutron spontaneously converts to a proton and an electron. Unlike alpha particles, beta particles are not emitted with discrete energies but are ejected from the nucleus over a continuous energy spectrum. Beta particles are smaller than alpha particles, carry a single negative charge, and possess a lower specific ionization potential. Unshielded beta sources can constitute external hazards if the beta radiation is within a few centimeters of exposed skin surfaces and if the beta energy is greater than 70 keV. Beta sources shielded with certain metallic materials may produce bremsstrahlung (low energy x-ray) radiation which may also contribute to the external radiation exposure. Internally, beta particles have a much greater range than alpha particles in tissue. However, because they cause fewer ionizations per unit path length, beta particles deposit much less energy to small volumes of tissue and, consequently, inflict must less damage than alpha particles.

Positrons are identical to beta particles except that they have a positive charge. A positron is emitted from the nucleus of a neutron-deficient atom when a proton spontaneously transforms into a neutron. Alternatively, in cases where positron emission is not energetically possible, the neutron deficiency may be overcome by electron capture, whereby one of the orbital electrons is captured by the nucleus and united with a proton to form a neutron, or by annihilation radiation, whereby the combined mass of a positron and electron is converted into photon energy. The damage inflicted by positrons to small volumes of tissue is similar to that of beta particles.

Gamma radiations are photons emitted from the nucleus of a radioactive atom. X-rays, which are extra-nuclear in origin, are identical in form to gamma rays, but have slightly lower energy ranges. There are three main ways in which x- and gamma rays interact with matter: the photoelectric effect, the Compton effect, and pair production. All three processes yield electrons which then ionize or excite other atoms of the substance. Because of their high penetration ability, x- and gamma radiations are of most concern as external hazards.

Neutrons are emitted during nuclear fission reactions, along with two smaller nuclei, called fission fragments, and beta and gamma radiation. For radionuclides likely to be encountered at Superfund sites, the rate of spontaneous fission is minute and no significant neutron radiation is expected.

EXHIBIT 10-1

RADIOLOGICAL CHARACTERISTICS OF SELECTED RADIONUCLIDES FOUND AT SUPERFUND SITES[a]

Nuclide	Half-life[c]	Average Radiation Energies (MeV/decay)[b]		
		Alpha	Beta, Electron	x, Gamma
Am-241	4.32×10^{2} y	5.57×10^{0}	5.21×10^{-2}	3.25×10^{-2}
Am-243	7.38×10^{3} y	5.36×10^{0}	2.17×10^{-2}	5.61×10^{-2}
Ba-137m	2.55×10^{0} h	--	6.37×10^{-2}	5.98×10^{-1}
C-14	5.73×10^{3} y	--	4.95×10^{-2}	--
Ce-144	2.84×10^{2} d	--	9.22×10^{-2}	2.07×10^{-2}
Cm-243	2.85×10^{1} y	5.89×10^{0}	1.38×10^{-1}	1.35×10^{-1}
Cm-244	1.81×10^{1} y	5.89×10^{0}	8.59×10^{-3}	1.70×10^{-3}
Co-60	5.27×10^{0} y	--	9.65×10^{-2}	2.50×10^{0}
Cr-51	2.77×10^{1} d	--	3.86×10^{-3}	3.26×10^{-2}
Cs-134	2.06×10^{0} y	--	1.64×10^{-1}	1.55×10^{0}
Cs-135	2.30×10^{6} y	--	6.73×10^{-2}	--
Cs-137	3.00×10^{1} y	--	1.87×10^{-1}	--
Fe-59	4.45×10^{1} d	--	1.17×10^{-1}	1.19×10^{0}
H-3	1.23×10^{1} y	--	5.68×10^{-3}	--
I-129	1.57×10^{7} y	--	6.38×10^{-2}	2.46×10^{-2}
I-131	8.04×10^{0} d	--	1.92×10^{-1}	3.81×10^{-1}
K-40	1.28×10^{9} y	--	5.23×10^{-1}	1.56×10^{-1}
Mn-54	3.13×10^{2} d	--	4.22×10^{-3}	8.36×10^{-1}
Mo-99	6.60×10^{1} h	--	3.93×10^{-1}	1.50×10^{-1}
Nb-94	2.03×10^{4} y	--	1.68×10^{-1}	1.57×10^{0}
Np-237	2.14×10^{6} y	4.85×10^{0}	7.01×10^{-2}	3.46×10^{-2}
P-32	1.43×10^{1} d	--	6.95×10^{-1}	--
Pb-210	2.23×10^{1} y	--	3.80×10^{-2}	4.81×10^{-3}
Po-210	1.38×10^{2} d	5.40×10^{0}	8.19×10^{-8}	8.51×10^{-6}
Pu-238	8.77×10^{1} y	5.59×10^{0}	1.06×10^{-2}	1.81×10^{-3}
Pu-239	2.41×10^{4} y	5.24×10^{0}	6.74×10^{-3}	8.07×10^{-4}
Pu-240	6.54×10^{3} y	5.24×10^{0}	1.06×10^{-2}	1.73×10^{-3}
Pu-241	1.44×10^{1} y	1.22×10^{-4}	5.25×10^{-3}	2.55×10^{-6}
Pu-242	3.76×10^{5} y	4.97×10^{0}	8.73×10^{-3}	1.44×10^{-3}
Ra-226	1.60×10^{3} y	4.86×10^{0}	3.59×10^{-3}	6.75×10^{-3}
Ra-228	5.75×10^{0} y	--	1.69×10^{-2}	4.14×10^{-9}
Ru-106	3.68×10^{2} d	--	1.00×10^{-2}	--
S-35	8.74×10^{1} d	--	4.88×10^{-2}	--
Sr-89	5.05×10^{1} d	--	5.83×10^{-1}	8.45×10^{-5}
Sr-90	2.91×10^{1} y	--	1.96×10^{-1}	--
Tc-99	2.13×10^{5} y	--	1.01×10^{-1}	--
Tc-99m	6.02×10^{0} h	--	1.62×10^{-2}	1.26×10^{-1}
Th-230	7.70×10^{4} y	4.75×10^{0}	1.42×10^{-2}	1.55×10^{-3}
Th-232	1.41×10^{10} y	4.07×10^{0}	1.25×10^{-2}	1.33×10^{-3}
U-234	2.44×10^{5} y	4.84×10^{0}	1.32×10^{-2}	1.73×10^{-3}
U-235	7.04×10^{8} y	4.47×10^{0}	4.92×10^{-2}	1.56×10^{-1}
U-238	4.47×10^{9} y	4.26×10^{0}	1.00×10^{-2}	1.36×10^{-3}

[a] Source: ICRP 1983 (except Ba-137m data from Kocher 1981).
[b] Computed as the sum of the products of the energies and yields of individual radiations.
[c] Half-life expressed in years (y), days (d), and hours (h).

The activity per unit mass of a given radionuclide is called the specific activity, and is usually expressed in units of becquerels per gram (Bq/g) or curies per gram (Ci/g). The shorter the half-life of the radionuclide, the greater is its specific activity. For example, Co-60 has a radioactive half-life of about 5 years and a specific activity of $4x10^{13}$ Bq/g, whereas Np-237 has a half-life of 2 million years and a specific activity of $3x10^{7}$ Bq/g.

Several terms are used by health physicists to describe the physical interactions of different types of radiations with biological tissue, and to define the effects of these interactions on human health. One of the first terms developed was radiation exposure, which refers to the transfer of energy from a radiation field of x- or gamma rays to a unit mass of air. The unit for this definition of exposure is the roentgen (R), expressed as coulombs of charge per kilogram of air (1 R = $2.58x10^{-4}$ C/kg).

The term exposure is also defined as the physical contact of the human body with radiation. Internal exposure refers to an exposure that occurs when human tissues are subjected to radiations from radionuclides that have entered the body via inhalation, ingestion, injection, or other routes. External exposure refers to the irradiation of human tissues by radiations emitted by radionuclides located outside the body either dispersed in the air or water, on skin surfaces, or deposited on ground surfaces. All types of radiation may contribute to internal exposure, whereas only photon, beta, and neutron radiations contribute significantly to external exposure.

Ionizing radiation can cause deleterious effects on biological tissues only when the energy released during radioactive decay is absorbed in tissue. The absorbed dose (D) is defined as the mean energy imparted by ionizing radiation per unit mass of tissue. The SI unit of absorbed dose is the joule per kilogram, also assigned the special name the gray (1 Gy = 1 joule/kg). The conventional unit of absorbed dose is the rad (1 rad = 100 ergs per gram = 0.01 Gy).

For radiation protection purposes, it is desirable to compare doses of different types of radiation. The absorbed dose of any radiation divided by the absorbed dose of a reference radiation (traditionally 250 kVp x-rays) that produces the same biological endpoint is called the Relative Biological Effectiveness or RBE. For regulatory purposes, an arbitrary consensus RBE estimate called the Quality Factor or Q is often used. The dose equivalent (H) was developed to normalize the unequal biological effects produced from equal absorbed doses of different types of radiation. The dose equivalent is defined as:

$$H = DQN$$

where D is the absorbed dose, Q is a quality factor that accounts for the RBE of the type of radiation emitted, and N is the product of any additional modifying factors. Quality factors currently assigned by the International Commission on Radiological Protection (ICRP) include values of Q=20 for alpha particles, Q=10 for neutrons and protons, and Q=1 for beta particles, positrons, x-rays, and gamma rays (ICRP 1984). These factors may be interpreted as follows: on average, if an equal amount of energy is absorbed, an alpha particle will inflict approximately 20 times more damage to biological tissue than a beta particle or gamma ray, and twice as much damage as a neutron. The modifying factor is currently assigned a value of unity (N=1) for all radiations. The SI unit of dose equivalent is the sievert (Sv), and the conventional unit is the rem (1 rem = 0.01 Sv).

GENERAL HEALTH PHYSICS REFERENCES

Introduction to Health Physics (Cember 1983)

Atoms, Radiation, and Radiation Protection (Turner 1986)

Environmental Radioactivity (Eisenbud 1987)

The Health Physics and Radiological Health Handbook (Shleien and Terpilak 1984)

EFFECTIVE DOSE EQUIVALENT

The effective dose equivalent, H_E, is a weighted sum of dose equivalents to all organs and tissues (ICRP 1977, ICRP 1979), defined as:

$$H_E = \sum_T w_T H_T$$

where w_T is the weighting factor for organ or tissue T and H_T is the mean dose equivalent to organ or tissue T. The factor w_T, which is normalized so that the summation of all the organ weighting factors is equal to one, corresponds to the fractional contribution of organ or tissue T to the total risk of stochastic health effects when the body is uniformly irradiated. Similarly, the committed effective dose equivalent, $H_{E,50}$, is defined as the weighted sum of committed dose equivalents to all irradiated organs and tissues, as follows:

$$H_{E,50} = \sum_T w_T H_{T,50}$$

H_E and $H_{E,50}$ thus reflect both the distribution of dose among the various organs and tissues of the body and their assumed relative sensitivities to stochastic effects. The organ and tissue weighting factor values w_T are as follows: Gonads, 0.25; Breast, 0.15; Red Marrow, 0.12; Lungs, 0.12; Thyroid, 0.03; Bone Surface, 0.03; and Remainder, 0.30 (i.e., a value of $w_T = 0.06$ is applicable to each of the five remaining organs or tissues receiving the highest doses).

The dose delivered to tissues from radiations external to the body occurs only while the radiation field is present. However, the dose delivered to body tissues due to radiations from systemically incorporated radionuclides may continue long after intake of the nuclide has ceased. Therefore, internal doses to specific tissues and organs are typically reported in terms of the committed dose equivalent ($H_{T,50}$), which is defined as the integral of the dose equivalent in a particular tissue T for 50 years after intake (corresponding to a working lifetime).

When subjected to equal doses of radiation, organs and tissues in the human body will exhibit different cancer induction rates. To account for these differences and to normalize radiation doses and effects on a whole body basis for regulation of occupational exposure, the ICRP developed the concept of the effective dose equivalent (H_E) and committed effective dose equivalent ($H_{E,50}$), which are defined as weighted sums of the organ-specific dose equivalents (i.e., $\Sigma\, w_T H_T$) and organ-specific committed dose equivalents (i.e., $\Sigma w_T H_{T,50}$), respectively. Weighting factors, w_T, are based on selected stochastic risk factors specified by the ICRP and are used to average organ-specific dose equivalents (ICRP 1977, 1979). The effective dose equivalent is equal to that dose equivalent, delivered at a uniform whole-body rate, that corresponds to the same number (but possibly a dissimilar distribution) of fatal stochastic health effects as the particular combination of committed organ dose equivalents (see the box on this page).

A special unit, the working level (WL), is used to describe exposure to the short-lived radioactive decay products of radon (Rn-222). Radon is a naturally occurring radionuclide that is of particular concern because it is ubiquitous, it is very mobile in the environment, and it decays through a series of short-lived decay products that can deliver a significant dose to the lung when inhaled. The WL is defined as any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of 1.3×10^5 MeV of alpha energy. The working level month (WLM) is defined as the exposure to 1 WL for 170 hours (1 working month).

Radiation protection philosophy encourages the reduction of all radiation exposures as low as reasonably achievable (ALARA), in consideration of technical, economic, and social factors. Further, no practice involving radiation exposure should be adopted unless it provides a positive net benefit. In addition to these general guidelines, specific upper limits on radiation exposures and doses have been established by regulatory authorities as described in the following section.

Additional discussion on the measurement of radioactivity is provided in Sections 10.3 and 10.4, and the evaluation of radiation exposure and dose is discussed further in Section 10.5. Discussion of potential health impacts from ionizing radiation is presented in Section 10.6.

10.2 REGULATION OF RADIOACTIVELY CONTAMINATED SITES

Chapter 2 briefly describes the statutes, regulations, guidance, and studies related to the human health evaluation process for chemical contaminants. The discussion describes CERCLA, as amended by SARA, and the RI/FS process. Since radionuclides are classified as hazardous substances under CERCLA, this information is also applicable to radioactively contaminated sites. Chapter 2 also introduces the concept of compliance with applicable or relevant and appropriate requirements (ARARs) in federal and state environmental laws as required by SARA. Guidance on potential ARARs for the remediation of radioactively contaminated sites under CERCLA is available in the *CERCLA Compliance with Other Laws Manual* (EPA 1989c). Only a brief summary of regulatory authorities is presented here.

The primary agencies with regulatory authority for the cleanup of radioactively contaminated sites include EPA, the Nuclear Regulatory Commission (NRC), the Department of Energy (DOE), and state agencies. Other federal agencies, including the Department of Transportation (DOT) and Department of Defense (DOD), also have regulatory programs (but more limited) for radioactive materials. Also, national and international scientific advisory organizations provide recommendations related to radiation protection and radioactive waste management, but have no regulatory authority. The following is a brief description of the main functions and areas of jurisdiction of these agencies and organizations.

- EPA's authority to protect public health and the environment from adverse effects of radiation exposure is derived from several statutes, including the Atomic Energy Act, the Clean Air Act, the Uranium Mill Tailings Radiation Control Act (UMTRCA), the Nuclear Waste Policy Act, the Resource Conservation and Recovery Act (RCRA), and CERCLA. EPA's major responsibilities with regard to radiation include the development of federal guidance and standards, assessment of new technologies, and surveillance of radiation in the environment. EPA also has lead responsibility in the federal government for advising all federal agencies on radiation standards. EPA's radiation standards apply to many different types of activities involving all types of radioactive material (i.e., source, byproduct, special nuclear, and naturally occurring and accelerator produced radioactive material [NARM]). For some of the EPA standards, implementation and enforcement responsibilities are vested in other agencies, such as NRC and DOE.

- NRC licenses the possession and use of certain types of radioactive material at certain types of facilities. Specifically, the NRC is authorized to license source, byproduct, and special nuclear material. The NRC is not authorized to license NARM, although NARM may be partially subject to NRC regulation when it is associated with material licensed by the NRC. Most of DOE's operations are exempt from NRC's licensing and regulatory requirements, as are certain DOD activities involving nuclear weapons and the use of nuclear reactors for military purposes.

- DOE is responsible for conducting or overseeing radioactive material operations at numerous government-owned/contractor-operated facilities. DOE is also responsible for managing several inactive sites that contain radioactive waste, such as sites associated with the Formerly Utilized Sites Remedial Action Program (FUSRAP), the Uranium Mill Tailings Remedial Action Program (UMTRAP), the Grand Junction Remedial Action Program (GJRAP), and the Surplus Facilities

MAJOR FEDERAL LAWS FOR RADIATION PROTECTION

- Atomic Energy Act of 1954, Public Law 83-703 - established the Atomic Energy Commission as the basic regulatory authority for ionizing radiation.
- Energy Reorganization Act of 1974, Public Law 93-438 - amended the Atomic Energy Act, and established the Nuclear Regulatory Commission to regulate nondefense nuclear activities.
- Marine Protection, Research, and Sanctuaries Act of 1972, Public Law 92-532 - established controls for ocean disposal of radioactive waste.
- Safe Drinking Water Act, Public Law 93-523 - mandated regulation of radionuclides in drinking water.
- Clean Air Act Amendments of 1977, Public Law 95-95 - extended coverage of the Act's provisions to include radionuclides.
- Uranium Mill Tailings Radiation Control Act of 1978, Public Law 96-415 - required stabilization and control of byproduct materials (primarily mill tailings) at licensed commercial uranium and thorium processing sites.
- Low-Level Radioactive Waste Policy Act of 1980, Public Law 96-573 - made states responsible for disposal of LLRW generated within their borders and encouraged formation of inter-state compacts.
- Nuclear Waste Policy Act of 1982, Public Law 97-425 - mandated the development of repositories for the disposal of high-level radioactive waste and spent nuclear fuel.
- Low-Level Radioactive Waste Policy Act Amendments of 1985, Public Law 99-240 - amended LLRWPA requirements and schedules for establishment of LLRW disposal capacity.

Management Program (SFMP). DOE is authorized to control all types of radioactive materials at sites within its jurisdiction.

- Other federal agencies with regulatory programs applicable to radioactive waste include DOT and DOD. DOT has issued regulations that set forth packaging, labeling, record keeping, and reporting requirements for the transport of radioactive material (see 49 CFR Parts 171 through 179). Most of DOD's radioactive waste management activities are regulated by NRC and/or EPA. However, DOD has its own program for controlling wastes generated for certain nuclear weapon and reactor operations for military purposes. Other agencies, such as the Federal Emergency Management Agency (FEMA) and the Department of the Interior (DOI), may also play a role in radioactive waste cleanups in certain cases.

- States have their own authority and regulations for managing radioactive material and waste. In addition, 29 states (Agreement States) have entered into agreements with the NRC, whereby the Commission has relinquished to the states its regulatory authority over source, byproduct, and small quantities of special nuclear material. Both Agreement States and Nonagreement States can also regulate NARM. Such state-implemented regulations are potential ARARs.

- The National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP) provide recommendations on human radiation protection. The NCRP was chartered by Congress to collect, analyze, develop, and disseminate information and recommendations about radiation protection and measurements. The ICRP's function is basically the same, but on an international level. Although

neither the NCRP nor the ICRP have regulatory authority, their recommendations serve as the basis for many of the general (i.e., not source-specific) regulations on radiation protection developed at state and federal levels.

The standards, advisories, and guidance of these various groups are designed primarily to be consistent with each other, often overlapping in scope and purpose. Nevertheless, there are important differences between agencies and programs in some cases. It is important that these differences be well understood so that when more than one set of standards is potentially applicable to or relevant and appropriate for the same CERCLA site, RPMs will be able to evaluate which standards to follow. In general, determination of an ARAR for a site contaminated with radioactive materials requires consideration of the radioactive constituents present and the functional operations that generated the site, whose regulatory jurisdiction the site falls under, and which regulation is most protective, or if relevant and appropriate, most appropriate given site conditions.

For further information on radiation standards, advisories, and guidance, RPMs should consult the detailed ARARs guidance document (EPA 1989c), as well as EPA's ORP and/or Regional Radiation Program Managers.

10.3 DATA COLLECTION

Data collection needs and procedures for sites contaminated with radioactive substances are very similar to those described in Chapter 4 for chemically contaminated sites. There are, however, some basic differences that simplify data collection for radionuclides, including the relative ease and accuracy with which natural background radiation and radionuclide contaminants can be detected in the environment when compared with chemical contaminants.

The pathways of exposure and the mathematical models used to evaluate the potential health risks associated with radionuclides in the environment are similar to those used for evaluating chemical contaminants. Many of the radionuclides found at Superfund sites behave in the environment like trace metals. Consequently, the types of data needed for a radiation risk assessment are very similar to those required for a chemical contaminant risk assessment. For example, the environmental, land use, and demographic data needed and the procedures used to gather the data required to model fate and effect are virtually identical. The primary differences lie in the procedures used to characterize the radionuclide contaminants. In the sections that follow, emphasis is placed on the procedures used to characterize the radionuclide contaminants and not the environmental setting that affects their fate and effects, since the latter has been thoroughly covered in Chapter 4.

10.3.1 RADIATION DETECTION METHODS

Field and laboratory methods used to identify and quantify concentrations of radionuclides in the environment are, in many cases, more exact, less costly, and more easily implemented than those employed for chemical analyses. Selection of a radiometric method depends upon the number of radionuclides of interest, their activities and types of radiations emitted, as well as on the level of sensitivity required and the sample size available. In some cases, the selection process requires prior knowledge of the nature and extent of radioactive contamination present onsite. See the references provided in the box on page 10-12 for detailed guidance on sample collection and preparation, radiochemical procedures, and radiation counters and measurement techniques. The following discussion provides an overview of a few of the radiation detection techniques and instruments currently used to characterize sites contaminated with radioactive materials.

Field methods utilize instrumental techniques rather than radiochemical procedures to determine in-situ identities and concentrations of radionuclides, contamination profiles, and external beta/gamma exposure rates. Field instruments designed for radiation detection (see Exhibit 10-2) are portable, rugged, and relatively insensitive to wide fluctuations in temperature and humidity. At the same time, they are sensitive enough to discriminate between variable levels of background radiation from naturally occurring radionuclides and excess radiation due to radioactive waste. Because of the harsh conditions in which they are

EXHIBIT 10-2

TYPES OF FIELD RADIATION DETECTION INSTRUMENTS

Instruments	Range of Counting Rate and Other Characteristics	Typical Uses	Remarks
Beta-Gamma Surface Monitors[a]			
Portable Count Rate Meter (Thin Walled or Thin Window G-M Counter)	0-1,000; 0-10,000; 0-100,000 count/min	Surfaces, hands, clothing	Simple, reliable, battery powered
Alpha Surface Monitors			
Portable Air Proportional Counter with Probe	0-100,000 count/min over 100 cm^2	Surfaces, hands, clothing	Not accurate in high humidity; battery powered; fragile window
Portable Gas Flow Counter with Probe	0-100,000 count/min over 100 cm^2	Surfaces, hands, clothing	Not affected by the humidity; battery powered; fragile window
Portable Scintillation Counter with Probe	0-100,000 count/min over 100 cm^2	Surfaces, hands, clothing	Not affected by the humidity; battery powered; fragile window
Air Monitors			
Particle Samplers			
Filter Paper (High-volume)	40 ft^3/min (1.1 m^3/min)	For quick grab samples	Used intermittently; requires separate coutner
Filter Paper (Low-volume)	0.1 to 10 ft^3/min (0.003-0.3 m^3/min)	For continuous room air breathing zone monitoring	Used continuously; requires separate counter
Electrostatic Precipitator	3 ft^3/min (0.09 m^3/min)	For continuous monitoring	Sample deposited on cyclindrical shell; requires separate counter
Impinger	20 to 40 ft^3/min (0.6-1.1 m^3/min)	Alpha contamination	Special uses; requires separate counter
Tritium Monitors			
Flow ionization chambers	0.10 pCi/m^3/min	Continuous monitoring	May be sensitive to other sources of ionization

[a] None of these surface monitors is suitable for tritium detection.

Source: NCRP Report No. 57 (NCRP 1978).

RADIONUCLIDE MEASUREMENT PROCEDURES

Environmental Radiation Measurements (NCRP 1976)

Instrumentation and Monitoring Methods for Radiation Protection (NCRP 1978)

Radiochemical Analytical Procedures for Analysis of Environmental Samples (EPA 1979a)

Eastern Environmental Radiation Facility Radiochemistry Procedures Manual (EPA 1984a)

A Handbook of Radioactivity Measurement Procedures (NCRP 1985a)

sometimes operated, and because their detection efficiency varies with photon energy, all field instruments should be properly calibrated in the laboratory against National Bureau of Standards (NBS) radionuclide sources prior to use in the field. Detector response should also be tested periodically in the field against NBS check-sources of known activity.

Commonly used gamma-ray survey meters include Geiger-Muller (G-M) probes, sodium iodide (NaI(Tl)) crystals, and solid-state germanium diodes (Ge(Li)) coupled to ratemeters, scalers, or multichannel analyzers (MCAs). These instruments provide measurements of overall exposure rates in counts per minute, or microRoentgens or microrem per hour. However, only NaI and Ge(Li) detectors with MCAs provide energy spectra of the gamma rays detected and can therefore verify the identity of specific radionuclides. Thin window G-M detectors and Pancake (ionization) probes are used to detect beta particles. Alpha-particle surface monitors include portable air proportional, gas proportional, and zinc sulfide (ZnS) scintillation detectors, which all have very thin and fragile windows. The references in the box on this page provide additional information on several other survey techniques and instruments, such as aerial gamma surveillance used to map gamma exposure rate contours over large areas.

Laboratory methods involve both chemical and instrumental techniques to quantify low-levels of radionuclides in sample media. The preparation of samples prior to counting is an important consideration, especially for samples containing alpha- and beta-emitting radionuclides that either do not emit gamma rays or emit gamma rays of low abundance. Sample preparation is a multistep process that achieves the following three objectives: (1) the destruction of the sample matrix (primarily organic material) to reduce alpha- and beta-particle self-absorption; (2) the separation and concentration of radionuclides of interest to increase resolution and sensitivity; and (3) the preparation of the sample in a suitable form for counting. Appropriate radioactive tracers (i.e., isotopes of the radionuclides of interest that are not present in the sample initially, but are added to the sample to serve as yield determinants) must be selected and added to the sample before a radiochemical procedure is initiated.

For alpha counting, samples are prepared as thin-layer (low mass) sources on membrane filters by coprecipitation with stable carriers or on metal discs by electrodeposition. These sample filters and discs are then loaded into gas proportional counters, scintillation detectors, or alpha spectrometry systems for measurement (see Exhibit 10-3). In a proportional counter, the sample is immersed in a counting gas, usually methane and argon, and subjected to a high voltage field: alpha emissions dissociate the counting gas creating an ionization current proportional to the source strength, which is then measured by the system electronics. In a scintillation detector, the sample is placed in contact with a ZnS phosphor against the window of a photomultiplier (PM) tube: alpha particles induce flashes of light in the phosphor that are converted to an electrical current in the PM tube and measured. Using alpha spectrometry, the sample is placed in a holder in an evacuated chamber facing a solid-state, surface-barrier detector: alpha particles strike the detector and cause electrical impulses, which are sorted by strength into electronic bins and counted. All three systems yield results in counts per minute, which are then converted into activity units using detector- and radionuclide-specific calibration

EXHIBIT 10-3

TYPES OF LABORATORY RADIATION DETECTION INSTRUMENTS[a]

Type of Instrument	Typical Activity Range (mCi)	Typical Sample Form	Data Acquisition and Display
Gas Proportional Counters	10^{-7} to 10^{-3}	Film disc mount, gas	Ratemeter or scaler
Liquid-Scintillation Counters	10^{-7} to 10^{-3}	Up to 20 ml of liquid gel	Accessories for background subtraction, quench correction, internal standard, sample comparison
NaI (Tl) Cylindrical or Well Crystals	10^{-6} to 10^{-3}	Liquid, solid, or contained gas, <4 ml	Ratemeter
			Discriminators for measuring various energy regions
			Multichannel analyzer, or computer plus analog-to-digital converter
			Computational accessories for full-energy-peak identification, quantification, and spectrum stripping
Ionization Chambers	10^{2} to 10^{3}	Liquid, solid, or contained gas (can be large in size)	Ionization-current measurement; digital (mCi) readout, as in dose calibrators
Solid-state Detectors	10^{-2} to 10	Various	Multichannel analyzer or computer with various readout options

[a]Source: NCRP Report No. 58 (NCRP 1985a).

values. Alpha spectrometry is the only system, however, that can be used to identify specific alpha-emitting radionuclides.

For beta counting, samples are prepared both as thin-sources and as solutions mixed with scintillation fluid, similar in function to a phosphor. Beta-emitting sources are counted in gas proportional counters at higher voltages than those applied for alpha counting or in scintillation detectors using phosphors specifically constructed for beta-particle detection. Beta-emitters mixed with scintillation fluid are counted in 20 ml vials in beta-scintillation counters: beta-particle interactions with the fluid produce detectable light flashes. Like alpha detectors, beta detectors provide measurements in counts per minute, which are converted to activity units using calibration factors. It should be noted, however, that few detection systems are available for determining the identity of individual beta-emitting radionuclides, because beta particles are emitted as a continuous spectrum of energy that is difficult to characterize and ascribe to any specific nuclide.

It is advisable to count all samples intact in a known geometry on a NaI or Ge(Li) detector system prior to radiochemical analysis, because many radionuclides that emit gamma rays in sufficient abundance and energy can be detected and measured by this process. Even complex gamma-ray spectra emitted by multiple radionuclide sources can be resolved using Ge(Li) detectors, MCAs, and software packages, and specific radionuclide concentrations can be determined. If the sample activity is low or if gamma rays are feeble, then more rigorous alpha or beta analyses are advised.

10.3.2 REVIEWING AVAILABLE SITE INFORMATION

In Chapter 4, reference is made to reviewing the site data for chemical contaminants in accordance with Stage 1 of the Data Quality Objectives (DQO) process (see box on Page 4-4). This process also applies to radionuclides. For further guidance on the applicability of DQOs to radioactively contaminated sites, consult EPA's Office of Radiation Programs.

10.3.3 ADDRESSING MODELING PARAMETER NEEDS

Exhibits 4-1 and 4-2 describe the elements of a conceptual model and the types of information that may be obtained during a site sampling investigation. These exhibits apply to radioactively contaminated sites with only minor modifications. For example, additional exposure pathways for direct external exposure from immersion in contaminated air or water or from contaminated ground surfaces may need to be addressed for certain radionuclides; these exposure pathways are discussed further in subsequent sections. In addition, several of the parameters identified in these exhibits are not as important or necessary for radiological surveys. For example, the parameters that are related primarily to the modeling of organic contaminants, such as the lipid content of organisms, are typically not needed for radiological assessments.

10.3.4 DEFINING BACKGROUND RADIATION SAMPLING NEEDS

As is the case with a chemically contaminated site, the background characteristics of a radioactively contaminated site must be defined reliably in order to distinguish natural background radiation and fallout from the onsite sources of radioactive waste. With the possible exception of indoor sources of Rn-222, it is often possible to make these distinctions because the radiation detection equipment and analytical techniques used are very precise and sensitive. At a chemically contaminated site, there can be many potential and difficult-to-pinpoint offsite sources for the contamination found onsite, confounding the interpretation of field measurements. With a radioactively contaminated site, however, this is not usually a problem because sources of radionuclides are, in general, easier to isolate and identify. In fact, some radionuclides are so specifically associated with particular industries that the presence of a certain radioactive contaminant sometimes acts as a "fingerprint" to identify its source. Additional information on the sources of natural background and man-made radiation in the environment may be found in the references listed in the box on the next page.

NATURAL BACKGROUND RADIATION

Tritium in the Environment (NCRP 1979)

Ionizing Radiation: Sources and Effects (UNSCEAR 1982)

Exposure from the Uranium Series with Emphasis on Radon and its Daughters (NCRP 1984b)

Carbon-14 in the Environment (NCRP 1985c)

Environmental Radioactivity (Eisenbud 1987)

Population Exposure to External Natural Radiation Background in the United States (EPA 1987a)

Ionizing Radiation Exposure of the Population of the United States (NCRP 1987a)

Exposure of the Population of the United States and Canada from Natural Background Radiation (NCRP 1987b)

10.3.5 PRELIMINARY IDENTIFICATION OF POTENTIAL EXPOSURE

Identification of environmental media of concern, the types of radionuclides expected at a site, areas of concern (sampling locations), and potential routes of radionuclide transport through the environment is an important part of the radiological risk assessment process. Potential media of concern include soil, ground water, surface water, air, and biota, as discussed in Chapter 4. Additional considerations for radioactively contaminated sites are listed below.

- Usually a very limited number of radionuclides at a site contribute significantly to the risk. During the site scoping meeting, it is appropriate to consult with a health physicist not only to develop a conceptual model of the facility, but also to identify the anticipated critical radionuclides and pathways.

- In addition to the environmental media identified for chemically contaminated sites, radioactively contaminated sites should be examined for the potential presence of external radiation fields. Many radionuclides emit both beta and gamma radiation, which can create significant external exposures.

- There are other components in the environment that may or may not be critical exposure pathways for the public, but that are very useful indicators of the extent and type of contamination at a site. These components include sediment, aquatic plants, and fish, which may concentrate and integrate the radionuclide contaminants that may be (or have been) present in the aquatic environment at a site. Accordingly, though some components of the environment may or may not be important direct routes of exposure to man, they can serve as indicators of contamination.

10.3.6 DEVELOPING A STRATEGY FOR SAMPLE COLLECTION

The discussions in Chapter 4 regarding sample location, size, type, and frequency apply as well to radioactively contaminated sites with the following additions and qualifications. First, the resolution and sensitivity of radioanalytical techniques permit detection in the environment of most radionuclides at levels that are well below those that are considered potentially harmful. Analytical techniques for nonradioactive chemicals are usually not this sensitive.

For radionuclides, continuous monitoring of the site environment is important, in addition to the sampling and monitoring programs described in Chapter 4. Many field devices that measure external gamma radiation, such as continuous radon monitors and high pressure ionization chambers, provide a real time continuous record of radiation exposure levels and radionuclide concentrations. Such devices are useful for determining the temporal variation of radiation

levels at a contaminated site and for comparing these results to the variability observed at background locations. Continuous measure-ments provide an added level of resolution for quantifying and characterizing radiological risk.

Additional factors that affect the frequency of sampling for radionuclides, besides those discussed in Chapter 4, include the half-lives and the decay products of the radionuclides. Radionuclides with short half-lives, such as Fe-59 (half-life = 44.5 days), have to be sampled more frequently because relatively high levels of contamination can be missed between longer sampling intervals. The decay products of the radionuclides must also be considered, because their presence can interfere with the detection of the parent nuclides of interest, and because they also may be important contributors to risks.

10.3.7 QUALITY ASSURANCE AND QUALITY CONTROL (QA/QC) MEASURES

The QA/QC concepts described in Chapter 4 also apply to sampling and analysis programs for radionuclides, although the procedures differ. Guidance regarding sampling and measurement of radionuclides and QA/QC protocols for their analyses are provided in the publications listed in the box on this page.

The QA/QC protocols used for radionuclide analysis were not developed to meet the evidential needs of the Superfund program; however, it is likely that many of the current radiological QA/QC guidance would meet the intent of Superfund requirements. Some areas where radiological QA/QC guidance may not meet the intent of Superfund are listed below.

- The degree of standardization for radiochemical procedures may be less rigorous in the QA/QC protocols than that required for chemical labs under the Contract Laboratory Program (CLP). In radiochemical laboratories, several different techniques may be used to analyze for a specific radionuclide in a given matrix with comparable results. The CLP requires all participating chemical laboratories to use standardized techniques.
- The required number and type of QC blanks are fewer for radionuclide samples. For example, a "trip" blank is not generally used because radionuclide samples are less likely to be contaminated from direct exposure to air than are samples of volatile organics.

Limited guidance is available that specifies field QA/QC procedures (see the box on this page). These and other issues related to QA/QC guidance for radiological analyses are discussed further in the Section 10.4.

RADIONUCLIDE MEASUREMENT QA/QC PROCEDURES

Quality Control for Environmental Measurements Using Gamma-Ray Spectrometry (EPA 1977b)

Quality Assurance Monitoring Programs (Normal Operation) - Effluent Streams and the Environment (NRC 1979)

Upgrading Environmental Radiation Data (EPA 1980)

Handbook of Analytical Quality Control in Radioanalytical Laboratories (EPA 1987b)

QA Procedures for Health Labs Radiochemistry (American Public Health Association 1987)

10.4 DATA EVALUATION

Chapter 5 describes the procedures for organizing and evaluating data collected during a site sampling investigation for use in risk assessment. The ten-step process outlined for chemical data evaluation is generally applicable to the evaluation of radioactive contaminants, although many of the details must be modified to accommodate differences in sampling and analytical methods.

10.4.1 COMBINING DATA FROM AVAILABLE SITE INVESTIGATIONS

All available data for the site should be gathered for evaluation and sorted by environmental medium sampled, analytical methods, and sampling periods. Decisions should be made, using the process described in Section 5.1, to combine, evaluate individually, or eliminate specific data for use in the quantitative risk assessment.

10.4.2 EVALUATING ANALYTICAL METHODS

As with chemical data, radiological data should be grouped according to the types of analyses performed to determine which data are appropriate for use in quantitative risk assessment. Analytical methods for measuring radioactive contaminants differ from those for measuring organic and inorganic chemicals. Standard laboratory procedures for radionuclide analyses are presented in references, such as those listed in the box on page 10-12. Analytical methods include alpha, beta, and gamma spectrometry, liquid scintillation counting, proportional counting, and chemical separation followed by spectrometry, depending on the specific radionuclides of interest.

Laboratory accreditation procedures for the analysis of radionuclides also differ. Radionuclide analyses are not currently conducted as part of the Routine Analytical Services (RAS) under the Superfund CLP. However, these analyses may be included under Special Analytical Services (SAS). The EPA Environmental Radioactivity Intercomparison Program, coordinated by the Nuclear Radiation Assessment Division of the Environmental Monitoring Systems Laboratory in Las Vegas (EMSL-LV), provides quality assurance oversight for participating radiation measurement laboratories (EPA 1989b). Over 300 federal, state, and private laboratories participate in some phase of the program, which includes analyses for a variety of radionuclides in media (e.g., water, air, milk, and food) with activity concentrations that approximate levels that may be encountered in the environment. Similar intercomparison programs for analysis of thermoluminescent dosimeters (TLDs) for external radiation exposure rate measurements are conducted by the DOE Environmental Measurements Laboratory (EML) and the DOE Radiological and Environmental Services Laboratory (RESL).

In both cases, these intercomparison programs are less comprehensive than the CLP in terms of facility requirements other than analysis of performance evaluation samples, such as laboratory space and procedural requirements, instrumentation, training, and quality control. However, until such time as radiation measurements become fully incorporated in the CLP, use of laboratories that successfully participate in these intercomparison studies may be the best available alternative for ensuring high-quality analytical data. Regardless of laboratory accreditation, all analytical results should be carefully scrutinized and not accepted at face value.

As discussed in Chapter 5 for chemical analyses, radioanalytical results that are not specific for a particular radionuclide (e.g., gross alpha, gross beta) may have limited usefulness for quantitative risk assessment. They can be useful as a screening tool, however. External gamma exposure rate data, although thought of as a screening measurement, can be directly applied as input data for a quantitative risk assessment.

10.4.3 EVALUATING QUANTITATION LIMITS

Lower limits of detection (LLDs), or quantitation limits, for standard techniques for most radionuclide analyses are sufficiently low to ensure the detection of nuclides at activity concentrations well below levels of concern. There are exceptions, however: some radionuclides with very low specific activities, long half-lives, and/or low-energy decay emissions (e.g., I-129, C-14) are difficult to detect precisely using standard techniques. To achieve lower LLDs, a laboratory may: (1) use more sensitive measurement techniques and/or chemical extraction procedures; (2) analyze larger sample sizes; or (3) increase the counting time of the sample. A laboratory may also choose to apply all three options to increase detection capabilities. Exhibit 10-4 presents examples of typical LLDs using standard analytical techniques.

The same special considerations noted for chemical analyses would also apply for

EXHIBIT 10-4

EXAMPLES OF LOWER LIMITS OF DETECTION (LLD) FOR SELECTED RADIONUCLIDES USING STANDARD ANALYTICAL METHODS[a]

Isotope	Sample Media[b]	LLD pCi	LLD Bq	Methodology
Co-60	-Water	10	0.4	Gamma Spectrometry
	-Soil (dry wt.)	0.1	0.004	Gamma Spectrometry
	-Biota (wet wt.)[c]	0.1	0.004	Gamma Spectrometry
	-Air[d]	25	0.9	Gamma Spectrometry
Sr-90	-Water	1	0.04	Radiochemistry
Cs-137	-Water	10	0.4	Gamma Spectrometry
		0.3	0.01	Radiochemistry
	-Soil (dry wt.)	1	0.04	Gamma Spectrometry
		0.3	0.01	Radiochemistry
	-Biota (wet wt.)	1	0.04	Gamma Spectrometry
		0.3	0.01	Radiochemistry
	-Air	30	1	Gamma Spectrometry
Pb-210	-Water	0.2	0.007	Radiochemistry
	-Soil (dry wt.)	0.2	0.007	Radiochemistry
	-Biota (wet wt.)	0.2	0.007	Radiochemistry
	-Air	5	0.2	Radiochemistry
Ra-226	-Water	100	4	Gamma Spectrometry
		0.1	0.004	Radiochemistry
		0.1	0.004	Radon Daughter Emanation
	-Soil (dry wt.)	0.1	0.004	Radon Daughter Emanation
	-Biota (wet wt.)	0.1	0.004	Radon Daughter Emanation
	-Air	1	0.04	Alpha Spectrometry
Th-232	-Water	0.02	0.0007	Alpha Spectrometry
	-Soil (dry wt.)	0.2	0.007	Radiochemistry
	-Biota (wet wt.)	0.02	0.0007	Alpha Spectrometry
	-Air	0.3	0.01	Alpha Proportional Counter
U-234	-Water	0.02	0.0007	Alpha Spectrometry
U-235	-Soil (dry wt.)	0.1	0.004	Alpha Spectrometry
U-238	-Biota (wet wt.)	0.01	0.0004	Alpha Spectrometry
	-Air	0.2	0.007	Alpha Spectrometry

(continued)

EXHIBIT 10-4 (continued)

EXAMPLES OF LOWER LIMITS OF DETECTION (LLD) FOR SELECTED RADIONUCLIDES USING STANDARD ANALYTICAL METHODS[a]

Isotope	Sample Media[b]	LLD pCi	LLD Bq	Methodology
Pu-238	-Water	0.02	0.0007	Alpha Spectrometry
Pu-239	-Soil (dry wt.)	0.1	0.004	Alpha Spectrometry
Pu-240	-Biota (wet wt.)	0.01	0.0004	Alpha Spectrometry
	-Air	0.2	0.007	Alpha Spectrometry

[a] Source: U.S. Environmental Protection Agency Eastern Environmental Radiation Facility (EPA-EERF), Department of Energy Environmental Measurements Laboratory (DOE-EML), and commercial laboratories. Note that LLDs are radionuclide-, media-, sample size-, and laboratory-specific: higher and lower LLDs than those reported above are possible. The risk assessor should request and report the LLDs supplied by the laboratory performing the analyses.

[b] Nominal sample sizes: water (1 liter), soil (1 kg dry wt.), biota (1 kg wet wt.), and air (1 filter sample).

[c] Biota includes vegetation, fish, and meat.

[d] Air refers to a sample of 300 m^3 of air collected on a filter, which is analyzed for the radionuclide of interest.

radionuclides that are not detected in any samples from a particular medium, but are suspected to be present at a site. In these cases, three options may be applied: (1) re-analyze the sample using more sensitive methods; (2) use the LLD value as a "proxy" concentration to evaluate the potential risks at the detection limit; or (3) evaluate the possible risk implication of the radionuclide qualitatively. An experienced health physicist should decide which of these three options would be most appropriate.

When multiple radionuclides are present in a sample, various interferences can occur that may reduce the analytical sensitivity for a particular radionuclide. Also, in some areas of high background radioactivity from naturally occurring radionuclides, it may be difficult to differentiate background contributions from incremental site contamination. It may be possible to eliminate such interferences by radiochemical separation or special instrumental techniques.

A sample with activity that is nondetectable should be reported as less than the appropriate sample and radionuclide-specific LLD value. However, particular caution should be exercised when applying this approach to radionuclides that are difficult to measure and possess unusually high detection limits, as discussed previously. In most cases where a potentially important radionuclide contaminant is suspected, but not detected, in a sample, the sample should be reanalyzed using more rigorous radiochemical procedures and more sophisticated detection techniques.

If radionuclide sample data for a site are reported without sample-specific radionuclide quantitation limits, the laboratory conducting the analyses should be contacted to determine the appropriate LLD values for the analytical techniques and sample media.

10.4.4 EVALUATING QUALIFIED AND CODED DATA

Various data qualifiers and codes may be attached to problem data from inorganic and organic chemical analyses conducted under the CLP as shown in Exhibits 5-4 and 5-5. These include laboratory qualifiers assigned by the laboratory conducting the analysis and data validation qualifiers assigned by personnel involved in data validation. These qualifiers pertain to QA/QC problems and generally indicate questions concerning chemical identity, chemical concentration, or both. No corresponding system of qualifiers has been developed for radioanalytical data, although certain of the CLP data qualifiers might be adopted for use in reporting radioanalytical data. The health physicist should define and evaluate any qualifiers attached to data for radionuclide analyses. Based on the discussions in Chapter 5, the references on methods listed above, and professional judgment, the health physicist should eliminate inappropriate data from use in the risk assessment.

10.4.5 COMPARING CONCENTRATIONS DETECTED IN BLANKS WITH CONCENTRATIONS DETECTED IN SAMPLES

The analysis of blank samples (e.g., laboratory or reagent blanks, field blanks, calibration blanks) is an important component of a proper radioanalytical program. Analysis of blanks provides a measure of contamination introduced into a sample during sampling or analysis activities.

The CLP provides guidance for inorganic and organic chemicals that are not common laboratory contaminants. According to this guidance, if a blank contains detectable levels of any uncommon laboratory chemical, site sample results should be considered positive only if the measured concentration in the sample exceeds five times the maximum amount detected in any blank. Samples containing less than five times the blank concentration should be classified as nondetects, and the maximum blank-related concentration should be specified as the quantitation limit for that chemical in the sample. Though they are not considered to be common laboratory contaminants, radionuclides should not be classified as nondetects using the above CLP guidance. Instead, the health physicist should evaluate all active sample preparation and analytical procedures for possible sources of contamination.

10.4.6 EVALUATING TENTATIVELY IDENTIFIED RADIONUCLIDES

Because radionuclides are not included on the Target Compound List (TCL), they may be classified as tentatively identified compounds (TICs) under CLP protocols. In reality, however, radioanalytical techniques are sufficiently sensitive that the identity and quantity of radionuclides of potential concern at a site can be determined with a high degree of confidence. In some cases, spectral or matrix interferences may introduce uncertainties, but these problems usually can be overcome using special radiochemical and/or instrumental methods. In cases where a radionuclide's identity is not sufficiently well-defined by the available data set: (1) further analyses may be performed using more sensitive methods, or (2) the tentatively identified radionuclide may be included in the risk assessment as a contaminant of potential concern with notation of the uncertainty in its identity and concentration.

10.4.7 COMPARING SAMPLES WITH BACKGROUND

It is imperative to select, collect, and analyze an appropriate number of background samples to be able to distinguish between onsite sources of radionuclide contaminants from radionuclides expected normally in the environment. Background measurements of direct radiation and radionuclide concentrations in all media of concern should be determined at sampling locations geologically similar to the site, but beyond the influence of the site. Screening measurements (e.g., gross alpha, beta, and gamma) should be used to determine whether more sensitive radionuclide-specific analyses are warranted. Professional judgment should be used by the health physicist to select appropriate background sampling locations and analytical techniques. The health physicist should also determine which naturally occurring radionuclides (e.g., uranium, radium, or thorium) detected onsite should be eliminated from the quantitative risk assessment. All man-made radionuclides detected in samples collected should, however, be retained for further consideration.

10.4.8 DEVELOPING A SET OF RADIONUCLIDE DATA AND INFORMATION FOR USE IN A RISK ASSESSMENT

The process described in Section 5.8 for selection of chemical data for inclusion in the quantitative risk assessment generally applies for radionuclides as well. One exception is the lack of CLP qualifiers for radionuclides, as discussed previously. Radionuclides of concern should include those that are positively detected in at least one sample in a given medium, at levels significantly above levels detected in blank samples and significantly above local background levels. As discussed previously, the decision to include radionuclides not detected in samples from any medium but suspected at the site based on historical information should be made by a qualified health physicist.

10.4.9 GROUPING RADIONUCLIDES BY CLASS

Grouping radionuclides for consideration in the quantitative risk assessment is generally unnecessary and inappropriate. Radiation dose and resulting health risk is highly dependent on the specific properties of each radionuclide. In some cases, however, it may be acceptable to group different radioisotopes of the same element that have similar radiological characteristics (e.g., Pu-238/239/240, U-235/238) or belong to the same decay series. Such groupings should be determined very selectively and seldom offer any significant advantage.

10.4.10 FURTHER REDUCTION IN THE NUMBER OF RADIONUCLIDES

For sites with a large number of radionuclides detected in samples from one or more media, the risk assessment should focus on a select group of radionuclides that dominate the radiation dose and health risk to the critical receptors. For example, when considering transport through ground water to distant receptors, transit times may be very long; consequently, only radionuclides with long half-lives or radioactive progeny that are formed during transport may be of concern for that exposure pathway. For direct external exposures, high-energy gamma emitters are of principal

concern, whereas alpha-emitters may dominate doses from the inhalation and ingestion pathways. The important radionuclides may differ for each exposure pathway and must be determined on their relative concentrations, half-lives, environmental mobility, and dose conversion factors (see Section 10.5 for discussion of dose conversion factors) for each exposure pathway of interest.

The total activity inventory and individual concentrations of radionuclides at a Superfund site will change with time as some nuclides decay away and others "grow in" as a result of radioactive decay processes. Consequently, it may be important to evaluate different time scales in the risk assessment. For example, at a site where Ra-226 (half-life = 1600 years) is the only contaminant of concern in soil at some initial time, the Pb-210 (half-life = 22.3 years) and Po-210 (half-life = 138 days) progeny will also become dominant contributors to the activity onsite over a period of several hundred years.

10.4.11 SUMMARIZING AND PRESENTING DATA

Presentation of results of the data collection and evaluation process will be generally the same for radionuclides and chemical contaminants. The sample table formats presented in Exhibits 5-6 and 5-7 are equally applicable to radionuclide data, except that direct radiation measurement data should be added, if appropriate for the radionuclides and exposure pathways identified at the site.

10.5 EXPOSURE AND DOSE ASSESSMENT

This section describes a methodology for estimating the radiation dose equivalent to humans from potential exposures to radionuclides through all pertinent exposure pathways at a remedial site. These estimates of dose equivalent may be used for comparison with radiation protection standards and criteria. However, this methodology has been developed for regulation of occupational radiation exposures for adults and is not completely applicable for estimating health risk to the general population. Section 10.7.2, therefore, describes a separate methodology for estimating health risk.

Chapter 6 describes the procedures for conducting an exposure assessment for chemical contaminants as part of the baseline risk assessment for Superfund sites. Though many aspects of the discussion apply to radionuclides, the term "exposure" is used in a fundamentally different way for radionuclides as compared to chemicals. For chemicals, exposure generally refers to the intake (e.g., inhalation, ingestion, dermal exposure) of the toxic chemical, expressed in units of mg/kg-day. These units are convenient because the toxicity values for chemicals are generally expressed in these terms. For example, the toxicity value used to assess carcinogenic effects is the slope factor, expressed in units of risk of lifetime excess cancers per mg/kg-day. As a result, the product of the intake estimate with the slope factor yields the risk of cancer (with proper adjustments made for absorption, if necessary).

Intakes by inhalation, ingestion, and absorption are also potentially important exposure pathways for radionuclides, although radionuclide intake is typically expressed in units of activity (i.e., Bq or Ci) rather than mass. Radionuclides that enter through these internal exposure pathways may become systemically incorporated and emit alpha, beta, or gamma radiation within tissues or organs. Unlike chemical assessments, an exposure assessment for radioactive contaminants can include an explicit estimation of the radiation dose equivalent. As discussed previously in Section 10.1, the dose equivalent is an expression that takes into consideration both the amount of energy deposited in a unit mass of a specific organ or tissue as a result of the radioactive decay of a specific radionuclide, as well as the relative biological effectiveness of the radiations emitted by that nuclide. (Note that the term dose has a different meaning for radionuclides [dose = energy imparted to a unit mass of tissue] than that used in Chapter 6 for chemicals [dose, or absorbed dose = mass penetrating into an organism].)

Unlike chemicals, radionuclides can have deleterious effects on humans without being taken into or brought in contact with the body. This is because high energy beta particles and photons

from radionuclides in contaminated air, water, or soil can travel long distances with only minimum attenuation in these media before depositing their energy in human tissues. External radiation exposures can result from either exposure to radionuclides at the site area or to radionuclides that have been transported from the site to other locations in the environment. Gamma and x-rays are the most penetrating of the emitted radiations, and comprise the primary contribution to the radiation dose from external exposures. Alpha particles are not sufficiently energetic to penetrate the outer layer of skin and do not contribute significantly to the external dose. External exposure to beta particles primarily imparts a dose to the outer layer skin cells, although high-energy beta radiation can penetrate into the human body.

The quantification of the amount of energy deposited in living tissue due to internal and external exposures to radiation is termed radiation dosimetry. The amount of energy deposited in living tissue is of concern because the potential adverse effects of radiation are proportional to energy deposition. The energy deposited in tissues is proportional to the decay rate of a radionuclide, and not its mass. Therefore, radionuclide quantities and concentrations are expressed in units of activity (e.g., Bq or Ci), rather than in units of mass.

Despite the fundamental difference between the way exposures are expressed for radionuclides and chemicals, the approach to exposure assessment presented in Chapter 6 for chemical contaminants largely applies to radionuclide contaminants. Specifically, the three steps of an exposure assessment for chemicals also apply to radionuclides: (1) characterization of the exposure setting; (2) identification of the exposure pathways; and (3) quantification of exposure. However, some of the methods by which these three steps are carried out are different for radionuclides.

10.5.1 CHARACTERIZING THE EXPOSURE SETTING

Initial characterization of the exposure setting for radioactively contaminated sites is virtually identical to that described in Chapter 6. One additional consideration is that, at sites suspected of having radionuclide contamination, a survey should be conducted to determine external radiation fields using any one of a number of field survey instruments (preferably, G-M tubes and NaI(Tl) field detectors) (see Exhibit 10-2). Health and safety plans should be implemented to reduce the possibility of radiation exposures that are in excess of allowable limits.

REFERENCES ON EXPOSURE ASSESSMENT FOR RADIONUCLIDES

Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents (NRC 1977)

Radiological Assessment: A Textbook on Environmental Dose Analysis (Till and Meyer 1983)

Models and Parameters for Environmental Radiological Assessments (Miller 1984)

Radiological Assessment: Predicting the Transport, Bioaccumulation, and Uptake by Man of Radionuclides Released to the Environment (NCRP 1984a)

Background Information Document, Draft EIS for Proposed NESHAPS for Radionuclides, Volume I, Risk Assessment Methodology (EPA 1989a)

Screening Techniques for Determining Compliance with Environmental Standards (NCRP 1989)

10.5.2 IDENTIFYING EXPOSURE PATHWAYS

The identification of exposure pathways for radioactively contaminated sites is very similar to that described in Chapter 6 for chemically contaminated sites, with the following additional guidance.

- In addition to the various ingestion, inhalation, and direct contact pathways described in Chapter 6, external exposure to penetrating radiation should also be considered. Potential external exposure

pathways to be considered include immersion in contaminated air, immersion in contaminated water, and radiation exposure from ground surfaces contaminated with beta- and photon-emitting radionuclides.

- As with nonradioactive chemicals, environmentally dispersed radionuclides are subject to the same chemical processes that may accelerate or retard their transfer rates and may increase or decrease their bioaccumulation potentials. These transformation processes must be taken into consideration during the exposure assessment.

- Radionuclides undergo radioactive decay that, in some respects, is similar to the chemical or biological degradation of organic compounds. Both processes reduce the quantity of the hazardous substance in the environment and produce other substances. (Note, however, that biological and chemical transformations can never alter, i.e., either increase or decrease, the radioactivity of a radionuclide.) Radioactive decay products can also contribute significantly to the radiation exposure and must be considered in the assessment.

- Chapter 6 presents a series of equations (Exhibits 6-11 through 6-19) for quantification of chemical exposures. These equations and suggested default variable values may be used to estimate radionuclide intakes as a first approximation, if the equations are modified by deleting the body weight and averaging time from the denominator. However, depending upon the characteristics of the radionuclides of concern, consideration of radioactive decay and ingrowth of radioactive decay products may be important additions, as well as the external exposure pathways.

- Chapter 6 also refers to a number of computer models that are used to predict the behavior and fate of chemicals in the environment. While those models may be suitable for evaluations of radioactive contaminants in some cases, numerous models have been developed specifically for evaluating the transport of radionuclides in the environment and predicting the doses and risks to exposed individuals. In general, models developed specifically for radiological assessments should be used. Such models include, for example, explicit consideration of radioactive decay and ingrowth of radioactive decay products. (Contact ORP for additional guidance on the fate and transport models recommended by EPA.)

10.5.3 QUANTIFYING EXPOSURE: GENERAL CONSIDERATIONS

One of the primary objectives of an exposure assessment is to make a reasonable estimate of the maximum exposure to individuals and critical population groups. The equation presented in Exhibit 6-9 to calculate intake for chemicals may be considered to be applicable to exposure assessment for radionuclides, except that the body weight and averaging time terms in the denominator should be omitted. However, as discussed previously, exposures to radionuclides include both internal and external exposure pathways. In addition, radiation exposure assessments do not end with the calculation of intake, but take the calculation an additional step in order to estimate radiation dose equivalent.

The radiation dose equivalent to specified organs and the effective dose equivalent due to intakes of radionuclides by inhalation or ingestion are estimated by multiplying the amount of each radionuclide inhaled or ingested times appropriate dose conversion factors (DCFs), which represent the dose equivalent per unit intake. As noted previously, the effective dose equivalent is a weighted sum of the dose equivalents to all irradiated organs and tissues, and represents a measure of the overall detriment. *Federal Guidance Report No. 11* (EPA 1988) provides DCFs for each of over 700 radionuclides for both inhalation and ingestion exposures. It is important to note, however, that these DCFs were developed for regulation of occupational exposures

to radiation and may not be appropriate for the general population.

Radionuclide intake by inhalation and ingestion is calculated in the same manner as chemical intake except that it is not divided by body weight or averaging time. For radionuclides, a reference body weight is already incorporated into the DCFs, and the dose is an expression of energy deposited per gram of tissue.

If intake of a radionuclide is defined for a specific time period (e.g., Bq/year), the dose equivalent will be expressed in corresponding terms (e.g., Sv/year). Because systemically incorporated radionuclides can remain within the body for long periods of time, internal dose is best expressed in terms of the committed effective dose equivalent, which is equal to the effective dose equivalent over the 50-year period following intake.

External exposures may be determined by monitoring and sampling of the radionuclide concentrations in environmental media, direct measurement of radiation fields using portable instrumentation, or by mathematical modeling. Portable survey instruments that have been properly calibrated can display dose rates (e.g., Sv/hr), and dose equivalents can be estimated by multiplying by the duration of exposure to the radiation field. Alternatively, measured or predicted concentrations in environmental media may be multiplied by DCFs, which relate radionuclide concentrations on the ground, in air, or in water to external dose rates (e.g., Sv/hr per Bq/m^2 for ground contamination or Sv/hr per Bq/m^3 for air or water immersion).

The dose equivalents associated with external and internal exposures are expressed in identical units (e.g., Sv), so that contributions from all pathways can be summed to estimate the total effective dose equivalent value and prioritize risk from different sources.

In general, radiation exposure assessments need not consider acute toxicity effects. Acute exposures are of less concern for radionuclides than for chemicals because the quantities of radionuclides required to cause adverse effects from acute exposure are extremely large and such levels are not normally encountered at Superfund sites. Toxic effects from acute radiation exposures are possible when humans are exposed to the radiation from large amounts of radioactive materials released during a major nuclear plant accident, such as Chernobyl, or during above-ground weapons detonations. Consequently, the exposure and risk assessment guidance for radionuclides presented in this chapter is limited to situations causing chronic exposures to low levels of radioactive contaminants.

10.5.4 QUANTIFYING EXPOSURE: DETERMINING EXPOSURE POINT CONCENTRATIONS

The preferred method for estimating the concentration of chemical or radioactive contaminants at those places where members of the public may come into contact with them is by direct measurement. However, this will not be possible in many circumstances and it may be necessary, therefore, to use environmental fate and transport models to predict contaminant concentrations. Such modeling would be necessary, for example: (1) when it is not possible to obtain representative samples for all radionuclides of concern; (2) when the contaminant has not yet reached the potential exposure points; and (3) when the contaminants are below the limits of detection but, if present, can still represent a significant risk to the public.

Numerous fate and transport models have been developed to estimate contaminant concentrations in ground water, soil, air, surface water, sediments, and food chains. Models developed for chemical contaminants, such as those discussed in Chapter 6, may also be applied to radionuclides with allowance for radioactive decay and ingrowth of decay products. There are also a number of models that have been developed specifically for radionuclides. These models are similar to the models used for toxic chemicals but have features that make them convenient to use for radionuclide pathway analysis, such as explicit consideration of radioactive decay and daughter ingrowth. Available models for use in radiation risk assessments range in complexity from a series of hand calculations to major computer codes. For example, NRC Regulatory Guide 1.109 presents a methodology that may be used to manually estimate dose equivalents from a variety of

exposure pathways (NRC 1977). Examples of computerized radiological assessment models include the AIRDOS-EPA code and the EPA-PRESTO family of codes, which are used extensively by EPA to estimate exposures and doses to populations following atmospheric releases of radionuclides and releases from a low-level waste disposal facility, respectively. Guidance on selection and use of the various models can be obtained from the EPA Office of Radiation Programs.

Exhibit 6-10, Example of Table Format for Summarizing Exposure Concentrations, may be used for radionuclide contaminants, except that radionuclide concentrations are expressed in terms of activity per unit mass or volume of the environmental medium (e.g., Bq/kg, Bq/L) rather than mass.

10.5.5 QUANTIFYING EXPOSURE: ESTIMATING INTAKE AND DOSE EQUIVALENT

Section 6.6 presents a description of the methods used to estimate intake rates of contaminants from the various exposure pathways. Exhibits 6-11 to 6-19 present the equations and input assumptions recommended for use in intake calculations. In concept, those equations and assumptions also apply generally to radionuclides, except that the body weight and averaging time terms in the denominators should be omitted. However, as discussed previously, the product of these calculations for radionuclides is an estimate of the radionuclide intake, expressed in units of activity (e.g., Bq), as opposed to mg/kg-day. In addition, the endpoint of a radiation exposure assessment is radiation dose, which is calculated using DCFs as explained below. As explained previously, dose equivalents calculated in the following manner should be used to compare with radiation protection standards and criteria, not to estimate risk.

Internal Exposure. Exhibits 6-11, 6-12, 6-14, 6-17, 6-18, and 6-19 present simplified models for the ingestion of water, food, and soil as pathways for the intake of environmental contaminants. The recommended assumptions for ingestion rates and exposure durations are applicable to radionuclide exposures and may be used to estimate the intake rates of radionuclides by these pathways. As noted previously, however, these intake estimates for radionuclides should not be divided by the body weight or averaging time. These intake rates must be multiplied by appropriate DCF values in order to obtain committed effective dose equivalent values. The more rigorous and complex radionuclide pathway models noted previously typically require much more extensive input data and may include default parameter values that differ somewhat from the values recommended in these exhibits.

Exhibit 6-16 presents the equation and assumptions used to estimate the contaminant intake from air. For radionuclides, the dose from inhalation of contaminated air is determined as the product of the radionuclide concentration in air (Bq/m^3), the breathing rate (m^3 per day or year), exposure duration (day or year), and the inhalation DCF (Sv per Bq inhaled). The result of this calculation is the committed effective dose equivalent, in units of Sv.

Chapter 6 points out that dermal absorption of airborne chemicals is not an important route of uptake. This point is also true for most radionuclides, except airborne tritiated water vapor, which is efficiently taken into the body through dermal absorption. In order to account for this route of uptake, the inhalation DCF for tritium includes an adjustment factor to account for dermal absorption.

External Exposure. Immersion in air containing certain beta-emitting and/or photon-emitting radioactive contaminants can also result in external exposures. Effective dose equivalents from external exposure are calculated as the product of the airborne radionuclide concentration (Bq/m^3), the external DCF for air immersion (Sv/hr per Bq/m^3), and the duration of exposure (hours).

Exhibits 6-13 and 6-15 illustrate the dermal uptake of contaminants resulting from immersion in water or contact with soil. This route of uptake can be important for many organic chemicals; however, dermal uptake is generally not an important route of uptake for radionuclides, which have small dermal permeability constants. External radiation exposure due to submersion in water contaminated with radionuclides is possible and is similar to external exposure due to

immersion in air. However, because of the shielding effects of water and the generally short durations of such exposures, immersion in water is typically of lesser significance. The product of the radionuclide concentration in water (Bq/m^3), the relevant DCF (Sv/hr per Bq/m^3), and the duration of exposure (hours) yields effective dose equivalent.

The third external exposure pathway of potential significance is irradiation from radionuclides deposited on the ground surface. Effective dose equivalents resulting from this pathway may be estimated as the product of the soil surface concentration (Bq/m^2) of photon-emitting radionuclides of concern, the external DCF for ground surface exposure (Sv/hr per Bq/m^2), and the duration of exposure (hours).

10.5.6 COMBINING INTAKES AND DOSES ACROSS PATHWAYS

The calculations described previously result in estimates of committed effective dose equivalents (Sv) from individual radionuclides via a large number of possible exposure pathways. Because a given population may be subject to multiple exposure pathways, the results of the exposure assessment should be organized by grouping all applicable exposure pathways for each exposed population. Risks from various exposure pathways and contaminants then can be integrated during the risk characterization step (see Section 10.7).

10.5.7 EVALUATING UNCERTAINTY

The radiation exposure assessment should include a discussion of uncertainty, that, at a minimum, should include: (1) a tabular summary of the values used to estimate exposures and doses and the range of these values; and (2) a summary of the major assumptions of the exposure assessment, including the uncertainty associated with each assumption and how it might affect the exposure and dose estimates. Sources of uncertainty that must be addressed include: (1) how well the monitoring data represent actual site conditions; (2) the exposure models, assumptions, and input variables used to estimate exposure point concentrations; and (3) the values of the variables used to estimate intakes and external exposures. More comprehensive discussions of uncertainty associated with radiological risk assessment are provided in the *Background Information Document for the Draft EIS for Proposed NESHAPS for Radionuclides* (EPA 1989a), *Radiological Assessment* (Till and Meyer 1983), and NCRP Report No. 76 (NCRP 1984a).

10.5.8 SUMMARIZING AND PRESENTING EXPOSURE ASSESSMENT RESULTS

Exhibit 6-22 presents a sample format for summarizing the results of the exposure assessment. The format may also be used for radionuclide contaminants except that the entries should be specified as committed effective dose equivalents (Sv) and the annual estimated intakes (Bq) for each radionuclide of concern. The intakes and dose estimates should be tabulated for each exposure pathway so that the most important radionuclides and pathways contributing to the total health risk may be identified.

The information should be organized by exposure pathway, population exposed, and current and future use assumptions. For radionuclides, however, it may not be necessary to summarize short-term and long-term exposures separately as specified for chemical contaminants.

10.6 TOXICITY ASSESSMENT

Chapter 7 describes the two-step process employed to assess the potential toxicity of a given chemical contaminant. The first step, hazard identification, is used to determine whether exposure to a contaminant can increase the incidence of an adverse health effect. The second step, dose-response assessment, is used to quantitatively evaluate the toxicity information and characterize the relationship between the dose of the contaminant administered or received and the incidence of adverse health effects in the exposed population.

There are certain fundamental differences between radionuclides and chemicals that somewhat simplify toxicity assessment for radionuclides. As discussed in the previous sections, the adverse effects of exposure to radiation are due to the energy deposited in sensitive tissue, which is referred to as the

radiation dose. In theory, any dose of radiation has the potential to produce an adverse effect. Accordingly, exposure to any radioactive substances is, by definition, hazardous.

Dose-response assessment for radionuclides is also more straightforward. The type of effects and the likelihood of occurrence of any one of a number of possible adverse effects from radiation exposure depends on the radiation dose. The relationship between dose and effect is relatively well characterized (at high doses) for most types of radiations. As a result, the toxicity assessment, within the context that it is used in this manual, need not be explicitly addressed in detail for individual radionuclides at each contaminated site.

The sections that follow provide a brief summary of the human and experimental animal studies that establish the hazard and dose-response relationship for radiation exposure. More detailed discussions of radiation toxicity are provided in publications of the National Academy of Sciences Committee on Biological Effects of Ionizing Radiation (BEIR), the United Nations Scientific Committee on Effects of Atomic Radiation (UNSCEAR), NRC, NCRP, and ICRP listed in the box on this page.

10.6.1 HAZARD IDENTIFICATION

The principal adverse biological effects associated with ionizing radiation exposures from radioactive substances in the environment are carcinogenicity, mutagenicity, and teratogenicity. Carcinogenicity is the ability to produce cancer. Mutagenicity is the property of being able to induce genetic mutation, which may be in the nucleus of either somatic (body) or germ (reproductive) cells. Mutations in germ cells lead to genetic or inherited defects. Teratogenicity refers to the ability of an agent to induce or increase the incidence of congenital malformations as a result of permanent structural or functional deviations produced during the growth and development of an embryo (more commonly referred to as birth defects). Radiation may induce other deleterious effects at acute doses above about 1 Sv, but doses of this magnitude are not normally associated with radioactive contamination in the environment.

REFERENCES ON HEALTH EFFECTS OF RADIATION EXPOSURE

Recommendations of the ICRP (ICRP 1977)

Limits for Intake of Radionuclides by Workers (ICRP 1979)

Influence of Dose and Its Distribution in Time on Dose-Response Relationships for Low-LET Radiations (NCRP 1980)

The Effects on Populations of Exposure to Low Levels of Ionizing Radiation (NAS 1980)

Induction of Thyroid Cancer by Ionizing Radiation (NCRP 1985b)

Lung Cancer Risk from Indoor Exposures to Radon Daughters (ICRP 1987)

Health Risks of Radon and Other Internally Deposited Alpha-Emitters (National Academy of Sciences 1988)

Ionizing Radiation: Sources, Effects, and Risks (UNSCEAR 1988)

Health Effects Models for Nuclear Power Plant Accident Consequence Analysis: Low-LET Radiation (NRC 1989)

As discussed in Section 10.1, ionizing radiation causes injury by breaking molecules into electrically charged fragments (i.e., free radicals), thereby producing chemical rearrangements that may lead to permanent cellular damage. The degree of biological damage caused by various types of radiation varies according to how spatially close together the ionizations occur. Some ionizing radiations (e.g., alpha particles) produce high density regions of ionization. For this reason, they are called high-LET (linear energy transfer) particles. Other types of radiation (e.g., x-rays, gamma rays, and beta particles) are called low-LET radiations because of the low density pattern of ionization they produce. In equal doses, the carcinogenicity and mutagenicity of

high-LET radiations may be an order of magnitude or more greater than those of low-LET radiations, depending on the endpoint being evaluated. The variability in biological effectiveness is accounted for by the quality factor used to calculate the dose equivalent (see Section 10.1).

Carcinogenesis. An extensive body of literature exists on radiation carcinogenesis in man and animals. This literature has been reviewed most recently by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the National Academy of Sciences Advisory Committee on the Biological Effects of Ionizing Radiations (NAS-BEIR Committee) (UNSCEAR 1977, 1982, 1988; NAS 1972, 1980, 1988). Estimates of the average risk of fatal cancer from low-LET radiation from these studies range from approximately 0.007 to 0.07 fatal cancers per sievert.

An increase in cancer incidence or mortality with increasing radiation dose has been demonstrated for many types of cancer in both human populations and laboratory animals (UNSCEAR 1982, 1988; NAS 1980, 1988). Studies of humans exposed to internal or external sources of ionizing radiation have shown that the incidence of cancer increases with increased radiation exposure. This increased incidence, however, is usually associated with appreciably greater doses and exposure frequencies than those encountered in the environment. Therefore, risk estimates from small doses obtained over long periods of time are determined by extrapolating the effects observed at high, acute doses. Malignant tumors in various organs most often appear long after the radiation exposure, usually 10 to 35 years later (NAS 1980, 1988; UNSCEAR 1982, 1988). Radionuclide metabolism can result in the selective deposition of certain radionuclides in specific organs or tissues, which, in turn, can result in larger radiation doses and higher-than-normal cancer risk in these organs.

Ionizing radiation can be considered pancarcinogenic, i.e., it acts as a complete carcinogen in that it serves as both initiator and promoter, and it can induce cancers in nearly any tissue or organ. Radiation-induced cancers in humans have been reported in the thyroid, female breast, lung, bone marrow (leukemia), stomach, liver, large intestine, brain, salivary glands, bone, esophagus, small intestine, urinary bladder, pancreas, rectum, lymphatic tissues, skin, pharynx, uterus, ovary, mucosa of cranial sinuses, and kidney (UNSCEAR 1977, 1982, 1988; NAS 1972, 1980, 1988). These data are taken primarily from studies of human populations exposed to high levels of radiation, including atomic bomb survivors, underground miners, radium dial painters, patients injected with thorotrast or radium, and patients who received high x-ray doses during various treatment programs. Extrapolation of these data to much lower doses is the major source of uncertainty in determining low-level radiation risks (see EPA 1989a). It is assumed that no lower threshold exists for radiation carcinogenesis.

On average, approximately 50 percent of all of the cancers induced by radiation are lethal. The fraction of fatal cancers is different for each type of cancer, ranging from about 10 percent in the case of thyroid cancer to 100 percent in the case of liver cancer (NAS 1980, 1988). Females have approximately 2 times as many total cancers as fatal cancers following radiation exposure, and males have approximately 1.5 times as many (NAS 1980).

Mutagenesis. Very few quantitative data are available on radiogenic mutations in humans, particularly from low-dose exposures. Some mutations are so mild they are not noticeable, while other mutagenic effects that do occur are similar to nonmutagenic effects and are therefore not necessarily recorded as mutations. The bulk of data supporting the mutagenic character of ionizing radiation comes from extensive studies of experimental animals (UNSCEAR 1977, 1982, 1988; NAS 1972, 1980, 1988). These studies have demonstrated all forms of radiation mutagenesis, including lethal mutations, translocations, inversions, nondisjunction, and point mutations. Mutation rates calculated from these studies are extrapolated to humans and form the basis for estimating the genetic impact of ionizing radiation on humans (NAS 1980, 1988; UNSCEAR 1982, 1988). The vast majority of the demonstrated mutations in human germ cells contribute to both increased mortality and illness (NAS 1980; UNSCEAR 1982). Moreover, the radiation protection community is generally in agreement that the probability of inducing genetic changes

increases linearly with dose and that no "threshold" dose is required to initiate heritable damage to germ cells.

The incidence of serious genetic disease due to mutations and chromosome aberrations induced by radiation is referred to as genetic detriment. Serious genetic disease includes inherited ill health, handicaps, or disabilities. Genetic disease may be manifest at birth or may not become evident until some time in adulthood. Radiation-induced genetic detriment includes impairment of life, shortened life span, and increased hospitalization. The frequency of radiation-induced genetic impairment is relatively small in comparison with the magnitude of detriment associated with spontaneously arising genetic diseases (UNSCEAR 1982, 1988).

Teratogenesis. Radiation is a well-known teratogenic agent. The developing fetus is much more sensitive to radiation than the mother. The age of the fetus at the time of exposure is the most important factor in determining the extent and type of damage from radiation. The malformations produced in the embryo depend on which cells, tissues, or organs in the fetus are most actively differentiating at the time of radiation exposure. Embryos are relatively resistant to radiation-induced teratogenic effects during the later stages of their development and are most sensitive from just after implantation until the end of organogenesis (about two weeks to eight weeks after conception) (UNSCEAR 1986; Brent 1980). Effects on nervous system, skeletal system, eyes, genitalia, and skin have been noted (Brent 1980). The brain appears to be most sensitive during development of the neuroblast (these cells eventually become the nerve cells). The greatest risk of brain damage for the human fetus occurs at 8 to 15 weeks, which is the time the nervous system is undergoing the most rapid differentiation and proliferation of cells (Otake 1984).

10.6.2 DOSE-RESPONSE RELATIONSHIPS

This section describes the relationship of the risk of fatal cancer, serious genetic effects, and other detrimental health effects to exposure to low levels of ionizing radiation. Most important from the standpoint of the total societal risk from exposures to low-level ionizing radiation are the risks of cancer and genetic mutations. Consistent with our current understanding of their origins in terms of DNA damage, these effects are believed to be stochastic; that is, the probability (risk) of these effects increases with the dose of radiation, but the severity of the effects is independent of dose. For neither induction of cancer nor genetic effects, moreover, is there any convincing evidence for a "threshold" (i.e., some dose level below which the risk is zero). Hence, so far as is known, any dose of ionizing radiation, no matter how small, might give rise to a cancer or to a genetic effect in future generations. Conversely, there is no way to be certain that a given dose of radiation, no matter how large, has caused an observed cancer in an individual or will cause one in the future.

Exhibit 10-5 summarizes EPA's current estimates of the risk of adverse effects associated with human exposure to ionizing radiation (EPA 1989a). Important points from this summary table are provided below.

- Very large doses (>1 Sv) of radiation are required to induce acute and irreversible adverse effects. It is unlikely that such exposures would occur in the environmental setting associated with a potential Superfund site.

- The risks of serious noncarcinogenic effects associated with chronic exposure to radiation include genetic and teratogenic effects. Radiation-induced genetic effects have not been observed in human populations, and extrapolation from animal data reveals risks per unit exposure that are smaller than, or comparable to, the risk of cancer. In addition, the genetic risks are spread over several generations. The risks per unit exposure of serious teratogenic effects are greater than the risks of cancer. However, there is a possibility of a threshold, and the exposures must occur over a specific period of time during gestation to cause the effect. Teratogenic effects can be induced only during the nine months of pregnancy. Genetic effects are induced during the 30-year reproductive generation and cancer can be induced at any point

EXHIBIT 10-5

SUMMARY OF EPA'S RADIATION RISK FACTORS[a]

Risk	Significant Exposure Period	Risk Factor Range
Low LET (Gy^{-1})		
Teratogenic:[b]		
Severe mental retardation	Weeks 8 to 15 of gestation	0.25-0.55
Genetic:		
Severe hereditary defects, all generations	30-year reproductive generation	0.006-0.11
Somatic:		
Fatal cancers	Lifetime	0.012-0.12
	In utero	0.029-0.10
All cancers	Lifetime	0.019-0.19
High LET (Gy^{-1})		
Genetic:		
Severe hereditary defects, all generations	30-year reproductive generation	0.016-0.29
Somatic:		
Fatal cancers	Lifetime	0.096-0.96
All cancers	Lifetime	0.15-1.5
Radon Decay Products (10^{-6} WLM^{-1})		
Fatal lung cancer	Lifetime	140-720

[a] In addition to the stochastic risks indicated, acute toxicity may occur at a mean lethal dose of 3-5 Sv with a threshold in excess of 1 Sv.

[b] The range assumes a linear, non-threshold dose-response. However, it is plausible that a threshold may exist for this effect.

during the lifetime. If a radiation source is not controlled, therefore, the cumulative risk of cancer may be many times greater than the risk of genetic or teratogenic effects due to the potentially longer period of exposure.

Based on these observations, it appears that the risk of cancer is limiting and may be used as the sole basis for assessing the radiation-related human health risks of a site contaminated with radionuclides.

For situations where the risk of cancer induction in a specific target organ is of primary interest, the committed dose equivalent to that organ may be multiplied by an organ-specific risk factor. The relative radiosensitivity of various organs (i.e., the cancer induction rate per unit dose) differs markedly for different organs and varies as a function of the age and sex of the exposed individual. Tabulations of such risk factors as a function of age and sex are provided in the *Background Information Document for the Draft Environmental Impact Statement for Proposed NESHAPS for Radionuclides* (EPA 1989a) for cancer mortality and cancer incidence.

10.7 RISK CHARACTERIZATION

The final step in the risk assessment process is risk characterization. This is an integration step in which the risks from individual radionuclides and pathways are quantified and combined where appropriate. Uncertainties also are examined and discussed in this step.

10.7.1 REVIEWING OUTPUTS FROM THE TOXICITY AND EXPOSURE ASSESSMENTS

The exposure assessment results should be expressed as estimates of radionuclide intakes by inhalation and ingestion, exposure rates and duration for external exposure pathways, and committed effective dose equivalents to individuals from all relevant radionuclides and pathways. The risk assessor should compile the supporting documentation to ensure that it is sufficient to support the analysis and to allow an independent duplication of the results. The review should also confirm that the analysis is reasonably complete in terms of the radionuclides and pathways addressed.

In addition, the review should evaluate the degree to which the assumptions inherent in the analysis apply to the site and conditions being addressed. The mathematical models used to calculate dose use a large number of environmental transfer factors and dose conversion factors that may not always be entirely applicable to the conditions being analyzed. For example, the standard dose conversion factors are based on certain generic assumptions regarding the characteristics of the exposed individual and the chemical and physical properties of the radionuclides. Also, as is the case for chemical contaminants, the environmental transfer factors used in the models may not apply to all settings.

Though the risk assessment models may include a large number of radionuclides and pathways, the important radionuclides and pathways are usually few in number. As a result, it is often feasible to check the computer output using hand calculations. This type of review can be performed by health physicists familiar with the models and their limitations. Guidance on conducting such calculations is provided in numerous references, including Till and Meyer (1983) and NCRP Report No. 76 (NCRP 1984a).

10.7.2 QUANTIFYING RISKS

Given that the results of the exposure assessment are virtually complete, correct, and applicable to the conditions being considered, the next step in the process is to calculate and combine risks. As discussed previously, the risk assessment for radionuclides is somewhat simplified because only radiation carcinogenesis needs to be considered.

Section 10.5 presents a methodology for estimating committed effective dose equivalents that may be compared with radiation protection standards and criteria. Although the product of these dose equivalents (Sv) and an appropriate risk factor (risk per Sv) yields an estimate of risk, the health risk estimate derived in such a manner is not completely applicable for members of the general public. A better estimate of risk may be computed using age- and sex-specific coefficients for individual organs receiving significant radiation

doses. This information may be used along with organ-specific dose conversion factors to derive slope factors that represent the age-averaged lifetime excess cancer incidence per unit intake for the radionuclides of concern. The Integrated Risk Information System (IRIS) and the Health Effects Assessment Summary Tables (HEAST) contain slope factor values for radionuclides of concern at remedial sites for each of the four major exposure pathways (inhalation, ingestion, air immersion, and ground-surface irradiation), along with supporting documentation for the derivation of these values (see Chapter 7 for more detail on IRIS).

The slope factors for the inhalation pathway should be multiplied by the estimated inhaled activity (derived using the methods presented in Section 6.6.3 and Exhibit 6-16, without division of the body weight and averaging time) for each radionuclide of concern to estimate risks from the inhalation pathway. Similarly, risks from the ingestion pathway should be estimated by multiplying the ingestion slope factors by the activity ingested for each radionuclide of concern (derived using the methods presented in Exhibits 6-11, 6-12, 6-14, 6-17, 6-18, and 6-19, without division by the body weight and averaging time). Estimates of the risk from the air immersion pathway should be computed by multiplying the appropriate slope factors by the airborne radionuclide concentration (Bq/m^3) and the duration of exposure. Risk from the ground surface pathway should be computed as the product of the slope factor, the soil concentration (Bq/m^2), and the duration of exposure for each radionuclide of concern.

The sum of the risks from all radionuclides and pathways yields the lifetime risk from the overall exposure. As discussed in Chapter 8, professional judgment must be used in combining the risks from various pathways, as it may not be physically possible for one person to be exposed to the maximum radionuclide concentrations for all pathways.

10.7.3 COMBINING RADIONUCLIDE AND CHEMICAL CANCER RISKS

Estimates of the lifetime risk of cancer to exposed individuals resulting from radiological and chemical risk assessments may be summed in order to determine the overall potential human health hazard associated with a site. Certain precautions should be taken, however, before summing these risks. First, the risk assessor should evaluate whether it is reasonable to assume that the same individual can receive the maximum radiological and chemical dose. It is possible for this to occur in some cases because many of the environmental transport processes and routes of exposure are the same for radionuclides and chemicals.

In cases where different environmental fate and transport models have been used to predict chemical and radionuclide exposure, the mathematical models may incorporate somewhat different assumptions. These differences can result in incompatibilities in the two estimates of risk. One important difference of this nature is how the cancer toxicity values (i.e., slope factors) were developed. For both radionuclides and chemicals, cancer toxicity values are obtained by extrapolation from experimental and epidemiological data. For radionuclides, however, human epidemiological data form the basis of the extrapolation, while for many chemical carcinogens, laboratory experiments are the primary basis for the extrapolation. Another even more fundamental difference between the two is that slope factors for chemical carcinogens generally represent an upper bound or 95th percent confidence limit value, while radionuclide slope factors are best estimate values.

In light of these limitations, the two sets of risk estimates should be tabulated separately in the final baseline risk assessment.

10.7.4 ASSESSING AND PRESENTING UNCERTAINTIES

Uncertainties in the risk assessment must be evaluated and discussed, including uncertainties in the physical setting definition for the site, in the models used, in the exposure parameters, and in the toxicity assessment. Monte Carlo uncertainty analyses are frequently performed as part of the uncertainty and sensitivity analysis for radiological risk assessments. A summary of the use of uncertainty analyses in support of radiological risk assessments is provided in NCRP Report No. 76 (NCRP 1984a), *Radiological Assessment* (Till and Meyer 1983), and in the *Background Information*

Document for the Draft EIS for Proposed NESHAPs for Radionuclides (EPA 1989a).

10.7.5 SUMMARIZING AND PRESENTING THE BASELINE RISK CHARACTERIZATION RESULTS

The results of the baseline risk characterization should be summarized and presented in an effective manner to assist in decision-making. The estimates of risk should be summarized in the context of the specific site conditions. Information should include the identity and concentrations of radionuclides, types and magnitudes of health risks predicted, uncertainties in the exposure estimates and toxicity information, and characteristics of the site and potentially exposed populations. A summary table should be provided in a format similar to that shown in Exhibit 6-22, as well as graphical presentations of the predicted health risks (see Exhibit 8-7).

10.8 DOCUMENTATION, REVIEW, AND MANAGEMENT TOOLS FOR THE RISK ASSESSOR, REVIEWER, AND MANAGER

The discussion provided in Chapter 9 also applies to radioactively contaminated sites. The suggested outline provided in Exhibit 9-1 may also be used for radioactively contaminated sites with only minor modifications. For example, the portions that uniquely pertain to the CLP program and noncarcinogenic risks are not needed. In addition, because radionuclide hazard and toxicity have been addressed adequately on a generic basis, there is no need for an extensive discussion of toxicity in the report.

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APPENDIX A

ADJUSTMENTS FOR ABSORPTION EFFICIENCY

This appendix contains example calculations for absorption efficiency adjustments that might be needed for Superfund site risk assessments. Absorption adjustments might be necessary in the risk characterization step to ensure that the site exposure estimate and the toxicity value for comparison are both expressed as absorbed doses or both expressed as intakes.

Information concerning absorption efficiencies might be found in the sections describing absorption toxicokinetics in HEAs, HEEDs, HEEPs, HADs, EPA drinking water quality criteria or ambient water quality criteria documents, or in ATSDR toxicological profiles. If there is no information on absorption efficiency by the oral/inhalation routes, one can attempt to find absorption efficiencies for chemically related substances. If no information is available, conservative default assumptions might be used. Contact ECAO for further guidance.

Adjustments may be necessary to match the exposure estimate with the toxicity value if one is based on an absorbed dose and the other is based on an intake (i.e., administered dose). Adjustments may also be necessary for different vehicles of exposure (e.g., water, food, or soil).

For the dermal route of exposure, the procedures outlined in Chapter 6 result in an estimate of the absorbed dose. Toxicity values that are expressed as administered doses will need to be adjusted to absorbed doses for comparison. This adjustment is discussed in Section A.1.

For the other routes of exposure (i.e., oral and inhalation), the procedures outlined in Chapter 6 result in an estimate of daily intake. If the toxicity value for comparison is expressed as an administered dose, no adjustment may be necessary (except, perhaps, for vehicle of exposure). If the toxicity value is expressed as an absorbed dose, however, adjustment of the exposure estimate (i.e., intake) to an absorbed dose is needed for comparison with the toxicity value. This adjustment is discussed in Section A.2.

Adjustments also may be necessary for different absorption efficiencies depending on the medium of exposure (e.g., contaminants ingested with food or soil might be less completely absorbed than contaminants ingested with water). This adjustment is discussed in Section A.3.

A.1 ADJUSTMENTS OF TOXICITY VALUE FROM ADMINISTERED TO ABSORBED DOSE

Because there are few, if any, toxicity reference values for dermal exposure, oral values are frequently used to assess risks from dermal

ACRONYMS FOR APPENDIX A

ATSDR = Agency for Toxic Substances and Disease Registry
ECAO = Environmental Criteria and Assessment Office
HAD = Health Assessment Document
HEA = Health Effects Assessment
HEED = Health and Environmental Effects Document
HEEP = Health and Environmental Effects Profile
RfD = Reference Dose
SF = Slope Factor

DEFINITIONS FOR APPENDIX A

Absorbed Dose. The amount of a substance penetrating the exchange boundaries of an organism after contact. Absorbed dose is calculated from the intake and the absorption efficiency. It usually is expressed as mass of a substance absorbed into the body per unit body weight per unit time (e.g., mg/kg-day).

Administered Dose. The mass of substance administered to an organism and in contact with an exchange boundary (e.g., gastrointestinal tract) per unit body weight per unit time (e.g., mg/kg-day).

Exposure Route. The way a chemical or physical agent comes in contact with an organism (i.e., by ingestion, inhalation, or dermal contact).

Intake. A measure of exposure expressed as the mass of substance in contact with the exchange boundary per unit body weight per unit time (e.g., mg/kg-day). Also termed the normalized exposure rate, equivalent to administered dose.

Reference Dose (RfD). The Agency's preferred toxicity value for evaluating noncarcinogenic effects resulting from exposures at Superfund sites. See specific entries for chronic RfD, subchronic RfD, and developmental RfD. The acronym RfD, when used without other modifiers, either refers generically to all types of RfDs or specifically to chronic RfDs; it never refers specifically to subchronic or developmental RfDs.

Slope Factor. A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime. The slope factor is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.

exposure. Most RfDs and some slope factors are expressed as the amount of substance administered per unit time and unit body weight, whereas exposure estimates for the dermal route of exposure are eventually expressed as absorbed doses. Thus, for dermal exposure to contaminants in water or in soil, it may be necessary to adjust an oral toxicity value from an administered to an absorbed dose. In the boxes to the right and on the next page are samples of adjustments for an oral RfD and an oral slope factor, respectively. If the oral toxicity value is already expressed as an absorbed dose (e.g., trichloroethylene), it is not necessary to adjust the toxicity value.

In the absence of any information on absorption for the substance or chemically related substances, one must assume an oral absorption efficiency. Assuming 100 percent absorption in an oral administration study that serves as the basis for an RfD or slope factor would be a non-conservative approach for estimating the dermal RfD or slope factor (i.e., depending on the type of chemical, the true absorbed dose might have been much lower than 100 percent, and hence an absorbed-dose RfD should similarly be much lower or the slope factor should be much higher). For example, some metals tend to be poorly absorbed

EXAMPLE: ADJUSTMENT OF AN ADMINISTERED TO AN ABSORBED DOSE RfD

An oral RfD, unadjusted for absorption, equals 10 mg/kg-day.

Other information (or an assumption) indicates a 20% oral absorption efficiency in the species on which the RfD is based.

The adjusted RfD that would correspond to the absorbed dose would be:

10 mg/kg-day x 0.20 = 2 mg/kg-day.

The adjusted RfD of 2 mg/kg-day would be compared with the amount estimated to be absorbed dermally each day.

(less than 5 percent) by the gastrointestinal tract. A relatively conservative assumption for oral absorption in the absence of appropriate information would be 5 percent.

EXAMPLE: ADJUSTMENT OF AN ADMINISTERED TO AN ABSORBED DOSE SLOPE FACTOR

An oral slope factor, unadjusted for absorption equals 1.6 $(mg/kg\text{-}day)^{-1}$.

Other information (or an assumption) indicates a 20% absorption efficiency in the species on which the slope factor is based.

The adjusted slope factor that would correspond to the absorbed dose would be:

$1.6(mg/kg\text{-}day)^{-1}/0.20 = 8\ (mg/kg\text{-}day)^{-1}$.

The adjusted slope factor of 8 $(mg/kg\text{-}day)^{-1}$ would be used to estimate the cancer risk associated with the estimated absorbed dose for the dermal route of exposure.

A.2 ADJUSTMENT OF EXPOSURE ESTIMATE TO AN ABSORBED DOSE

If the toxicity value is expressed as an absorbed rather than an administered dose, it may be necessary to convert the exposure estimate from an intake into an absorbed dose for comparison. An example of estimating an absorbed dose from an intake using an absorption efficiency factor is provided in the box in the top right corner. Do not adjust exposure estimates for absorption efficiency if the toxicity values are based on administered doses.

A.3 ADJUSTMENT FOR MEDIUM OF EXPOSURE

If the medium of exposure in the site exposure assessment differs from the medium of

EXAMPLE: ADJUSTMENT OF EXPOSURE ESTIMATE TO AN ABSORBED DOSE

The exposure assessment indicates that an individual ingests 40 mg/kg-day of the chemical from locally grown vegetables.

The oral RfD (or slope factor) for the chemical is based on an absorbed, not administered, dose.

The human oral absorption efficiency for the contaminant from food is known or assumed to be 10 percent.

The adjusted exposure, expressed as an absorbed dose for comparison with the RfD (or slope factor), would be:

40 mg/kg-day x 0.10 = 4 mg/kg-day.

exposure assumed by the toxicity value (e.g., RfD values usually are based on or have been adjusted to reflect exposure via drinking water, while the site medium of concern may be soil), an absorption adjustment may, on occasion, be appropriate. For example, a substance might be more completely absorbed following exposure to contaminated drinking water than following exposure to contaminated food or soil (e.g., if the substance does not desorb from soil in the gastrointestinal tract). Similarly, a substance might be more completely absorbed following inhalation of vapors than following inhalation of particulates. The selection of adjustment method will depend upon the absorption efficiency inherent in the RfD or slope factor used for comparison. To adjust a food or soil ingestion exposure estimate to match an RfD or slope factor based on the assumption of drinking water ingestion, an estimate of the relative absorption of the substance from food or soil and from water is needed. A sample calculation is provided in the box on the next page.

In the absence of a strong argument for making this adjustment or reliable information on relative absorption efficiencies, assume that the

EXAMPLE: ADJUSTMENT FOR MEDIUM OF EXPOSURE

The expected human daily intake of the substance in food or soil is estimated to be 10 mg/kg-day.

Absorption of the substance from drinking water is known or assumed to be 90%, and absorption of the substance from food or soil is known or assumed to be 30%.

The relative absorption of the substance in food or soil/drinking water is 0.33 (i.e., 30/90).

The oral intake of the substance, adjusted to be comparable with the oral RfD (based on an administered dose in drinking water), would be:

10 mg/kg-day x 0.33 = 3.3 mg/kg-day.

relative absorption efficiency between food or soil and water is 1.0.

If the RfD or slope factor is expressed as an absorbed dose rather than an administered dose, it is only necessary to identify an absorption efficiency associated with the medium of concern in the site exposure estimate. In the example above, this situation would translate into a relative absorption of 0.3 (i.e., 30/100).

APPENDIX B

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